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4 Introduction Introduction



From living, for life

# Introduction

Many of today's health problems can be attributed to an inadequate supply of energy to the body's cells, which can result in dysfunctioning of our natural regulatory systems. An unhealthy diet deficient in essential nutrients due to a lack of fresh fruit and vegetables, constant stress, lack of exercise and the presence of environmental toxins can all contribute to poor health. Another major factor is the age-related decrease of the body's natural enzyme production. To regain good health and retain it for as long as possible, it is extremely important to support biological regulatory processes. Self-regulation and homeostasis are the vital principles of the body.

Innovative "regulation medicine" is the major interest of Dr. Niedermaier Pharma GmbH. The company was founded in 1939 by the pharmacist and food chemist Dr Hans Niedermaier (1913–2003), with the vision of promoting health by natural means. His philosophy was "healing through self-healing". His daughter, pharmacist Dr Cordula Niedermaier-May, has been CEO since 2001. The company is based near Munich, Germany, and its core strengths are the development and production of herbal medicines.

Cascade fermentation, the result of many years of research, is now a patented process. Here begins the story of Regulat. Cascade fermented bioconcentrates, made from fresh fruit, vegetables and walnuts, are able to support biological regulatory processes. In addition to the original RegulatPro® Bio, which has been available since 2001, there an appropriate Regulat now exists for almost every area of life.

This compendium presents the latest findings on the effects of Regulat on the body. Results of basic scientific research and various studies in humans, in addition to years of clinic experience in therapeutic applications, reveal the many possibilities for use of the cascade-fermented product. Regulat can be taken orally and applied externally. It notably increases natural energy production in the cells, fine tunes enzymatic processes in the body, and corrects metabolic imbalances – in short, Regulat modulates and lays the foundations for good health and vital energy.







# Production of Regulat

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# Organic starting materials



# What is Regulat?

Regulats are fermented liquid concentrates made from fresh fruit, nuts and vegetables grown under certified organic conditions. The concentrates are obtained through cascade fermentation of the ingredients, a patented process regarded as the pinnacle of fermentation in its uniqueness throughout the world. By this method, the very essence of the plant is extracted, imbuing Regulats with their unique effectiveness. Numerous scientific studies have provided impressive confirmation of the results.

# Production of Regulat

# **Starting materials**

#### **Dates**

Dates are rich in vitamin  $B_5$  (pantothenic acid, known as the "fitness nutrient" for vitality and concentration), calcium (for bones and teeth), iron (for the red blood cells), copper (for blood formation), potassium (has diuretic effects and lowers the blood pressure) and tryptophan (an amino acid that is converted to the sleep hormone melatonin in the pineal gland and which helps you get to sleep).

#### **Figs**

Figs contain digestive enzymes and substances that kill bacteria; Figs are one of the oldest known medicinal plants for wound healing in the world. Figs also improve mood, combat nervousness, help with tiredness, loss of efficiency or loss of drive, improve concentration and alleviate menstrual symptoms.

#### **Walnuts**

Walnuts have a higher concentration of the essential unsaturated fatty acid alpha-linoleic acid than any other food; they also contain a high percentage of vitamin E. These have positive effects on the heart and blood vessels, particularly in lowering the "bad" LDL-cholesterol. Walnuts also contain B vitamins and vitamins A, C and E, which promote digestion and support important brain activities. Walnuts are thought of as "brain food".

#### Coconuts

Coconuts provide a rich supply of calcium (which is effective for osteoporosis), iron, phosphorus, sodium, unsaturated fatty acids, and the vitamins A, B<sub>2</sub> and C. They support metabolism in teeth and bones, improve vision, boost immune defences and promote the formation of blood and muscle tissue.



#### Lemons

Lemons are rich in vitamin C, one of the most important substances acting against infection and providing immune protection. Vitamin C stimulates the production of hydrochloric acid and the protein-splitting enzyme pepsin in the gastric mucosa. This in turn improves the functioning of protein, calcium and iron. Vitamin C from lemons help strengthen blood vessels, stop gum bleeding, promote cell growth and generally have a rejuvenating effect. The human body needs vitamin C for the synthesis of stress and sex hormones; endorphins are also produced.

#### Soy beans

Soy beans are an excellent source of protein. A good supply of protein is particularly important as protein deficiency curbs cell metabolism which can result in fatigue, apathy, nervousness and anxiety. Soya builds up new connective tissue and has a rejuvenating effect. Phosphatidyl choline and inositol contained in the beans calm the nerves and enhance mental concentration, renew the neurotransmitter acetyl choline and stimulate gastric acid production. Soya also removes fat from the liver, helps to improve vision and prevents the loss of libido.

#### **Onions**

Onions are loaded with allicin and other sulphur compounds. They supply zinc, folic acid, essential oils and flavonoids. Onions have a prophylactic effect against infection and disinfect the nasal cavity and oropharynx. They help lower the blood pressure and lipid levels, prevent arteriosclerosis and vascular disease, improve circulatory problems and relieve vein problems. So, overall, onions help strengthen the cardiovascular system. Onions also help with kidney and bladder problems and strengthen the mucosal lining of the gastrointestinal tract.

#### Celery

A high concentration of essential oils, especially terpenes, are found in celery. These oils have antibacterial and antimycotic effects in the mouth, pharynx, stomach and intestines. Even the kidneys, bladder and rest of the urinary tract are disinfected. Celery helps with inflammation and bladder weakness, as well as with digestive problems such as bloating or diarrhoea. The high concentration of vitamin B complex strengthens the nerves and aids brain functioning, as well as relieving nervous disorders, irritability and depression. Celery supplies important nutrients for healthy eyes, skin, hair and liver.

#### Soy sprouts

Soy bean sprouts contain a great deal of plant protein, essential fatty acids, minerals, trace elements and vitamins A, C and B<sub>2</sub>. They support the various functions of the stomach and liver, help maintain beautiful skin and appear to have a rejuvenating and revitalising effect.



#### **Artichokes**

The main active substance in artichokes is cynarine. This bitter substance protects the liver and stimulates hepatic cells to secrete more bile acids. It activates cholesterol release from the liver and slows down hepatic cholesterol synthesis. These actions work to help lower cholesterol levels. Carotene, B vitamins, vitamin C, iron and magnesium all regulate blood glucose levels, as well as having diuretic and anti-inflammatory effects.

#### Acerola

The acerola cherry is one of the richest natural sources of vitamin C. The antioxidant and immunostimulatory effect of vitamin C is considerably increased by the presence of provitamin A and flavonoids. B vitamins support nerve functions, while the minerals phosphorus and calcium act to strengthen bones.

#### Millet

Millet is rich in protein, silicic acid and lecithin, which promote hair and nail growth. B vitamins, iron, magnesium, copper and manganese improve concentration and memory.

#### **Peas**

Peas represent a rich supply of nucleic acids. These macromolecules, which also have the function of storing genetic information, are needed by our cells for division, repair and regeneration. Together with a high concentration of magnesium, peas have a rejuvenating effect, build up muscle tissue, strengthen the nerves, activate metabolism and promote cell growth.

#### Saffron

This spice is rich in essential oils and glucosides. Saffron has been used in gynaecology to treat menopause symptoms for centuries. It also relieves pain.

#### Curcuma

Curcuma (turmeric) stimulates the production of gastric and bile acids. The yellow pigments it contains have anticarcinogenic, antioxidant and anti-inflammatory effects.

All these starting materials for the Regulats ensure a broad spectrum of action and provide a wide range of enzymes. The valuable ingredients are obtained by gentle lactic acid fermentation, which makes them highly bioavailable for the human body, in a form that is easily absorbed via the mucosa of the mouth, stomach and intestines. The lactobacilli added during the fermentation process also provide probiotic components such as dextrorotatory lactic acid and peptidoglycans that act on the immune system.



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#### **Cascade fermentation**

Multi-stage fermentation according to the method developed by Dr. Niedermaier Pharma (Cascade Fermentation<sup>TM</sup>) is the result of many years of research. The process, which was patented in 2004 (EU Patent No. 1153549), is based on the functioning of the human digestive system: the subsequent, partial fermentation stages imitate the natural digestive cascades taking place in our bodies.

- **First step:** The fresh ingredients are macerated and loaded into a fermentation tank or bioreactor. Lactobacilli which produce dextrorotatory L(+) lactic acid are then added. Fermentation begins after about two days.
- **Second step:** After about three weeks, the first partial filtration is carried out. The filtrate is fermented again, with the addition of different lactobacilli. Applying the same principle, further fermentation steps are carried out, yielding progressively finer extracts.

• Third step: All fermentation fractions are combined, submitted to a final fermentation process and filtered. The starting materials are now in a uniquely fragmented form. The special, gentle production process means that no preservatives, chemical additives, sugar or alcohol need to be added.

#### **Biochemistry of cascade fermentation**

- Selected organically grown ingredients are fermented in stages by different micro-organisms.
- Lactobacilli use the sugar and other carbohydrates for energy.
- Proteins are broken down into amino acids, di-, tri- and oligopeptides.
- All bound secondary plant metabolites (phytochemicals), including >500 polyphenols, are released and accumulated in their synergy.
- New L(+) lactic acid and peptidoglycans are formed.
- New synergies of substances develop.
- The process generates precursors for the body's natural enzyme production.

### **Ingredients of Regulat products**

Regulat products contain unique enzyme fragments as well as essential amino acids, di-, tri- and oligopeptides, polyphenols, flavonoids, vitamins, minerals, peptidoglycans and dextrorotatory lactic acid. All the enzymes are extracted so they may be easily absorbed by the body. Proteins that may trigger allergic reactions are converted into non-allergenic oligopeptides and amino acids. These easily absorbed precursors are available for intracellular enzyme production; this in turn modulates the natural metabolic processes in the body. Dextrorotatory lactic acid strengthens the gut flora, peptidoglycans from the cell walls of the added lactic acid cultures boost the immune system.

Secondary plant metabolites, which have a high antioxidant potential, merit particular interest. These phytochemicals include phenolic acids (hydroxycinnamic acid), flavanones (hesperetin, naringenin), flavones, flavanols, procatechuic acid and ellagic acid. In addition to the antioxidant effects, many other health-promoting effects have been ascribed to the secondary plant metabolites:

- Antioxidant (protection against free radicals)
- Antimicrobial
- Immunomodulatory
- Anti-inflammatory
- Cholesterol lowering

- Blood glucose regulation
- Digestion enhancing
- Anticarcinogenic
- Antithrombotic
- Blood pressure regulation

Thanks to the cascade fermentation by which the products are prepared, the body can easily and rapidly absorb valuable protective substances and essential nutrients from the source foods. This enables their invigorating, regulatory, immunomodulatory and antioxidant potential to fully develop.

#### **In summary**

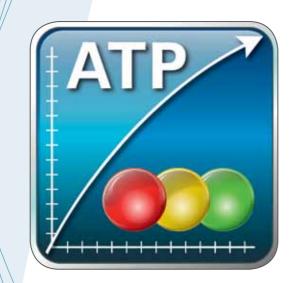
- Regulats are natural concentrates made from fresh fruits, nuts and vegetables that have been grown under strict organic conditions – they are foods, not medication.
- After time-consuming cascade fermentation, the valuable protective substances and essential nutrients are highly concentrated and in a form that can be absorbed immediately.
- The enzyme extract, effectively an "enzyme starter kit", can be immediately used by the body for intracellular enzyme production.

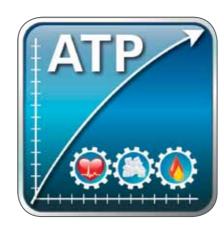


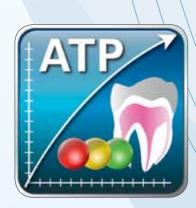


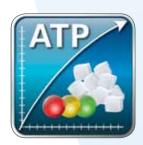
# The energy system

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# Energy – the motor of life

# The energy system

# ATP, the body's "fuel"

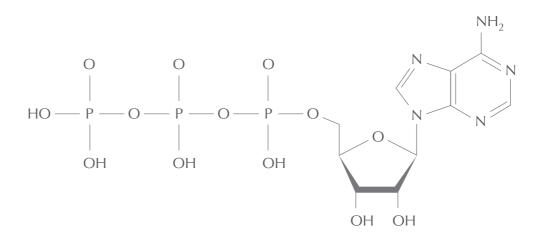
Energy is required for all the important processes in the body. The indispensable "fuel" is a substance called adenosine triphosphate (ATP) which is produced by mitochondria inside each cell. The ATP molecule (molecular formula C<sub>10</sub>H<sub>16</sub>N<sub>5</sub>O<sub>13</sub>P<sub>3</sub>) consists of adenine, the sugar ribose and a triphosphate moiety. The three phosphate groups are bound to each other by anhydride bonds. When enzymes cleave these bonds by hydrolysis, adenosine diphosphate (ADP) and adenosine monophosphate (AMP) plus phosphate(s) are formed. Each time such a high-energy bond is cleaved, energy is released for intracellular processes. ATP is therefore the universal supply of immediately available energy in every cell.

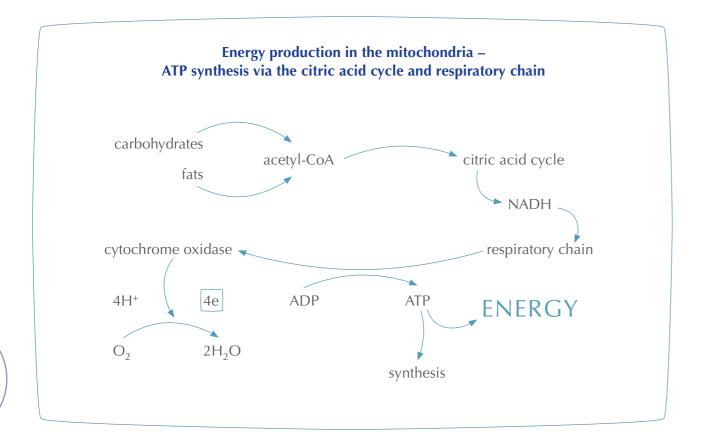
Conversely, energy is stored when ATP is formed. Briefly, the main steps are as follows: acetyl coenzyme A (acetyl-CoA, "activated acetic acid") is formed during the metabolism

of dietary carbohydrates and fats and is then broken down in the citric acid cycle. Hydrogen carriers such as reduced nicotinamide adenine dinucleotide (NADH) accumulate in this cycle and pass hydrogen and electrons on to oxygen in the respiratory chain – a process corresponding to an oxyhydrogen reaction. The electrons are not transferred directly to the oxygen molecule in the mitochondria but passed slowly along a controlled electron transport chain.

The enzyme cytochrome c oxidase has a pivotal role in the reduction of oxygen to water. Released energy is used to synthesise energy-rich ATP from ADP and phosphate, with the help of the enzyme ATP synthase (this is known as oxidative phosphorylation or respiratory-chain phosphorylation). ATP is then again available to meet the energy requirements for synthesis and physical performance.

#### Adenosine triphosphate (ATP) a great deal of energy is contained in the anhydride bonds between the phosphates





Most of the ATP in our bodies comes from oxidative phosphorylation. This energy-producing pathway is extremely effective. Comparing the aerobic breakdown of glucose in the mitochondria (i.e. glycolysis in the presence of oxygen - plus the citric acid cycle and respiratory chain) with the anaerobic breakdown of glucose to lactate in the cytosol (lactic acid fermentation), it can be seen that the ATP yield is almost twenty times higher in the presence of oxygen. One disadvantage, however, is that aerobic energy production also produces reactive oxygen species (ROS). But the body has developed antioxidant protective mechanisms to stop them causing any damage.

#### **Full speed ahead**

The body produces and breaks down some 10<sup>25</sup> ATP molecules per day – that is an incredible 10,000,000,000,000,000,000,000 molecules! It hardly seems possible, but the quantity of ATP an average adult produces and breaks down on a daily basis is almost equivalent to their body mass. An 80 kg man breaks down about 40 kg ATP per day, which he replaces by producing 40 kg of new ATP.

### The mitochondrion, the "powerhouse" of the cell

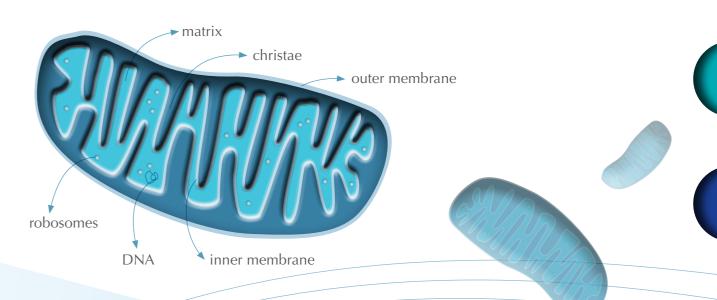
Mitochondria, considered to be the powerhouses of the cell, are found in the cytoplasm. These tiny organelles (measuring about 0.5-1.5 µm in diameter) contain their own genetic material and are surrounded by a double membrane. On average, each cell contains about 1500 mitochondria. This number is adjusted to the energy requirements of the cell; myocardial cells, which need a great deal of energy to function, may have as many as 4000 mitochondria.

The inner mitochondrial membrane presents many folds and protrusions (cristae), which greatly increase the surface area of the membrane. Mitochondria with a large number of narrow lamellar cristae (cristae type) function mainly in respiration and energy production. In contrast, mitochondria with broad tube-like folds (tubular type) contain many synthesising enzymes; they can be found in liver cells, for example.

Oxidative phosphorylation takes place in the inner mitochondrial membrane. This is where the complexes of the respiratory chain with the electron transport enzymes and ATP synthase are localised. The inner membrane surrounds the mitochondrial matrix, i.e. the inner fluid of the mitochondrion, which contains the enzymes involved in the citric acid cycle and β-oxidation (for the breakdown of fatty acids).

The endosymbiontic theory assumes that the mitochondria have developed from the symbiosis of aerobic bacteria with the precursors of today's eukaryotes (i.e., life forms whose cells contain a nucleus). Based on their possible bacterial origin, mitochondria are particularly sensitive to the effects of antibiotics.

#### **Structure of a mitochondrion:** the vital energy production of the cell takes place inside its inner membrane



### **Consequences of ATP deficiency**

Many current health problems are attributed to an inadequate supply of intracellular energy in the form of ATP. Too little ATP is produced and/or too much is used. The cells then lack the necessary energy to perform their chemical, osmotic or mechanical functions. The results are often loss of vitality, fatigue and exhaustion without any obvious cause. Other symptoms include concentration disorders, muscle weakness, pain and digestive problems.

Be it chronic fatigue syndrome (CFS), fibromyalgia, chronic muscle tension, burnout syndrome or chronic stress, the common factor in all these "modern" diseases is a lack of energy. With severe acute health problems and many chronic diseases such as diabetes, cancer, depression, Alzheimer's or cardiovascular disease, the cells are suffering from a lack of energy. Chronic inflammation and conditions with excessive immune responses such as multiple sclerosis, allergies and rheumatoid arthritis simply "devour" the energy in the cells.

If the cells lack ATP and therefore energy, the body has to mobilise its emergency reserves and consequently activate more oxygen to obtain the required energy. The result is increased oxidative stress, which is one of the main reasons for cell ageing. Furthermore, apoptosis (programmed cell death) starts when the ATP concentration is less than 40% of normal.

Mitochondrial function is weakened in many patients. The reason may be an unhealthy lifestyle or inadequate supply of micronutrients. An excessive use of antibiotics or medicines such as metformin (used for diabetes) are also under discussion today as possible causes. Mitochondrial repair is one of the prerequisites for restoring the body to a healthy, energy-rich state. However, reaching out for chocolate or glucose sweets in order to combat the perceived lack of energy is the wrong strategy. Mitochondrial dysfunction will not be overcome in this way, but extra calories will be deposited in the tissues as fat, and this can make health problems even worse.

### A lack of energy promotes metabolic stress and vice versa

Production, breakdown and conversion are continuous processes in our bodies. Oxygen has a key role in all of them. Reactive oxygen species (ROS) are formed as intermediate products during metabolism. Reactive nitrogen species such as nitrogen monoxide and its subsequent metabolite peroxynitrite also accumulate. Some of these are free radicals, i.e. atoms or molecules with at least one unpaired electron, which are usually very reactive. The

condition, which results from a predominance of reactive oxygen and nitrogen species, is referred to as oxidative or nitrosative stress or simply metabolic stress.

The body generates such reactive metabolites constantly, but to a much greater degree during illness. They are involved in many biological processes, sometimes have metabolic regulatory functions or act as secondary messengers

#### The main reactive oxygen and nitrogen species

#### **Free radicals**

- Atmospheric oxygen (bi-radical)
- Superoxide radical anion (O<sub>2</sub><sup>-•</sup>)
- Hydroperoxyl radical (HO<sub>2</sub>•)
- Hydroxyl radical (OH•)
- Alkyl and alkoxyl radical (R\*, RO\*)
- Peroxyl radikal (ROO•)
- Nitrogen monoxide or dioxide (NO•, NO2•)
- Hyperoxide anion O<sub>2</sub>•

#### Non-radical compounds

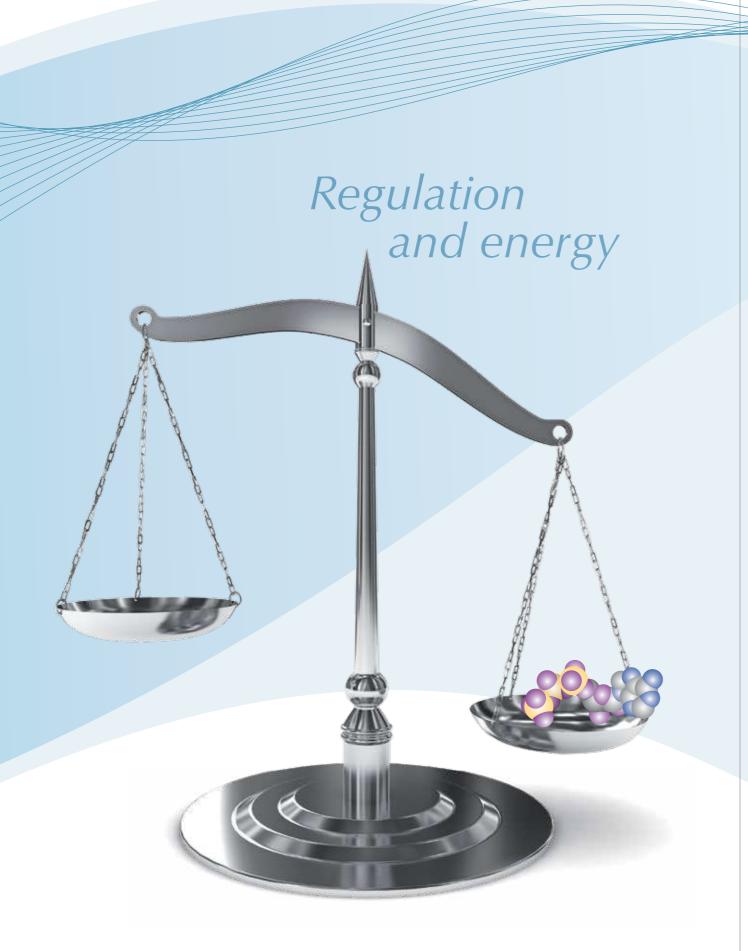
- Hydrogen peroxide (HOOH)
- Organic peroxide (ROOH)
- Hypohalogenated acids or their salts (HOCl, OCl-, organic chloramine)
- Peroxynitrite (ONOO<sup>-</sup>, ONOOH)
- Singleton oxygen (1O<sub>2</sub>)

 nitrogen monoxide or hydrogen peroxide, for example. Other reactive compounds, such as the hydroxyl radical (OH\*), hypochlorous acid (HOCl) or peroxynitrite (ONOO-), are particularly destructive and count as the ultimate cell killers. Too much of these toxic species can cause cell damage and accelerate cell ageing. Oxidative stress seems to be involved in the origin of many different diseases, including neurodegenerative disorders such as Parkinson's disease and Alzheimer's disease, arteriosclerosis and coronary artery disease, cancer, diabetes mellitus and its consequences, and inflammatory and rheumatic diseases.

Thanks to a regimented antioxidation system the body is well armed against oxidative (and nitrosative) stress. The antioxidant strategy of aerobic cells is equipped to inhibit the potentially toxic oxygen species or their derivatives at various stages of their production or reaction with biomolecules. However, under certain conditions such as metabolic or energy deficiencies, this protection against free radicals does not function properly. A supply of antioxidants is then important to restore or maintain the balance between pro- and antioxidant forces. This is vital for maintaining and restoring health and energy.

#### **In summary**

- Our bodies are working constantly to keep us alive. Regulat supports them.
- Many people suffer from a lack of intracellular energy (ATP), caused by diminishing mitochondrial function.
- ATP deficiency may lead to significant health problems.
- A lack of energy promotes both oxidative and nitrosative stress. This requires urgent intervention – with Regulat.
- Regulat does not supply any nutritional energy as it does not contain sugar or fats.
- Regulat intervenes in the basic metabolic and energy producing processes.
- Regulat boosts mitochondrial function.



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# Metabolic regulation (enzymatic regulation)

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Anti-inflammatory and antiallergic effects	3
Detoxification/deacidification	3
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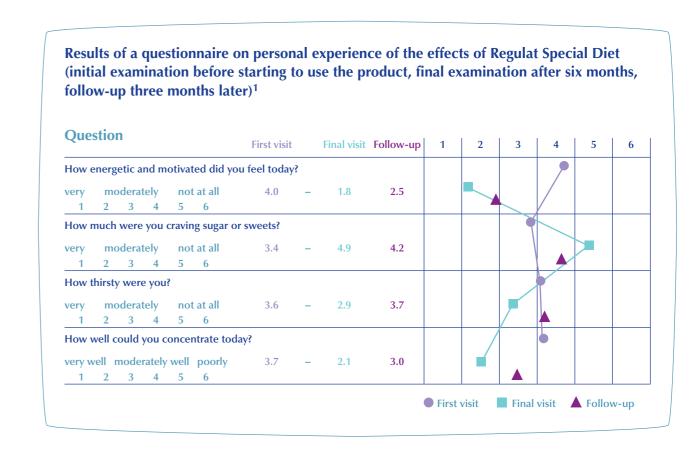
# How does Regulat work? Physiological mechanisms of action

# Improvement of energy metabolism

Energy imbalance in the body is a common problem today. The cells lack ATP, the fuel for all important physiological processes. For some years now, laboratories have been able to determine the levels of intracellular ATP. The ATP concentration is an indicator of whether an individual has sufficient energy supplies in their body. Years of experience with the use of Regulats have shown that Regulat-users have noticeably more energy. The subjective increase in energy has been confirmed by means of questionnaires in an open-label study including obese patients and people with those diabetes.1 After taking Regulats (10 ml Regulat

Special Diet, morning and evening) for six months, an average increase of 55% in energy and drive was reported, while concentration improved by 43%.

Similar outcomes were seen in a further prospective study under real-life conditions, also including patients with weight problems, metabolic syndrome or type-2 diabetes.<sup>2</sup> The questionnaire in this study also showed a clear subjective improvement in participants taking Regulats (10 ml RegulatPro® Metabolic, morning and evening). They felt more energetic motivated (+53%) and were able to concentrate better (+58%).



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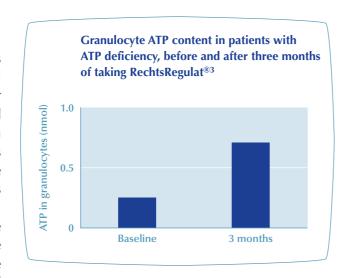
#### Intracellular ATP greatly increased

In this study, intracellular ATP measurements were made for the first time in four subjects.<sup>2</sup> Monocytes, lymphocytes and natural killer (NK) cells in heparinised blood were separated and lysed by density gradient centrifugation in order to determine the ATP released by means of chemiluminescence. Before intake of the Regulat began, the mean intracellular ATP was 0.68 µM (laboratory reference range >1.0), after six months it was 1.51  $\mu$ M – an increase of 122%. Three months later, during which time the subjects did not take any more Regulat, the mean was as much as 1.95 µM. Compared with baseline, intracellular ATP had increased by a mean of 187%. The further increase in ATP, even after discontinuation of the Regulat, is an indicator for the sustained recovery of mitochondrial function.

A large-scale prospective study looked further at the effects of Regulats on the ATP supply in humans with chronic lack of energy.<sup>3</sup> It included 31 patients who had been suffering for a prolonged time from at least two of the following symptoms or conditions (i.e., the study inclusion criteria):

- Significant lack of energy (n = 29)
- Chronic fatigue (n = 25)
- Chronic fatigue syndrome (n = 1)
- Burnout syndrome (n = 4)
- Depressive states (n = 19)
- Chronic inflammatory diseases (n = 22)
- Multisystem disease (n = 8)

The patients took Regulats (10 ml RechtsRegulat<sup>®</sup>, morning and evening) for three months, and experienced a mean increase in intracellular ATP of 55%. This study determined the ATP content of granulocytes (lab reference range 0.4–1.0 nmol). At the start of the study, 22 pa-



tients had an ATP deficiency. Taking Regulat for just three months resulted in a highly significant increase in ATP of 183% in these patients (from a mean of 0.25 nmol to 0.72 nmol).

The patients reported feeling much better. Physical fitness increased by an average of 60%, the ability to concentrate by 59%. There were also some astonishing improvements in specific and nonspecific symptoms. Almost all of the patients with chronic inflammation showed a clear alleviation or complete absence of symptoms.

# Improvement of mitochondrial dysfunction

Intracellular ATP represents an important way to measure mitochondrial function. The clear increase in ATP values when taking Regulats suggests significantly improved energy production in the mitochondria. It can therefore be assumed that Regulats improve mitochondrial dysfunction in a non-negligible way.

NB: RechtsRegulat® is the german name of RegulatPro® Bio.

The sustained effects on energy metabolism allow the body to replenish its energy reserves.

The energy gained in the cells through Regulats use is confirmed by ATP measurements in the lab. The objective extra energy correlates with the subjective increase in energy perceived by the treated patients.

#### In summary

- Patient who take Regulat feel more energetic, more motivated and can concentrate better.
- Low intracellular ATP values rise significantly.
- Mitochondrial dysfunction is reversed and function improved.

# Metabolic regulation (enzymatic regulation)

Almost all body functions are regulated by enzymes (which requires an enormous amount of ATP). Without enzymes, the millions of metabolic processes would not be possible. Regulats contain valuable building blocks for enzyme synthesis. The body can replace missing enzymes or repair non-functional enzymes; this allows fine-tuning of enzymatic processes involved in basal metabolism, detoxification and repair.

# **Immunoregulatory effects**

The main task of the immune system is to protect the body from bacterial or viral invasion and to protect it from cancer cells or foreign tissue. A distinction is made between nonspecific or innate immunity, which involves the activation of immune cells (e.g. neutrophil granulocytes, monocytes, macrophages, natural killer cells) and specific or adaptive immunity, characterised by "immunological memory" of the lymphocytes and production of specific antibodies. The two systems work closely together in defending the body from pathogens. The immune system

becomes less effective with age, contributing to the fact that older people are more susceptible to infections and certain types of cancer.

The immunoregulatory potential of Regulats has been demonstrated by various studies, including the *in vitro* analyses carried out by the Freising-Weihenstephan Centre of Life and Food Sciences, Technical University of Munich, and also a prospective randomised double-blind placebo-controlled trial.<sup>4</sup>

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#### Unique study of Regulat in healthy volunteers

A prospective randomised double-blind placebo-controlled trial in parallel group design was carried out. The study by Christiane Schön *et al.*<sup>4</sup> on Regulat in humans, published in the journal "Nutrition" in 2009, met the strictest scientific criteria, usually found only in clinical drug trials. This type of study is unusual for a food product.

The study enrolled 48 healthy men aged between 20 and 48 (normal weight, non-smokers, no vegetarians). None of them ate a huge amount of fruit and vegetables (about 200–280 g/day, which is about average in

Germany), and this remained unchanged throughout the study. The volunteers were randomised into two groups: 24 took Regulat (10 ml RechtsRegulat®, morning and evening) for four weeks and 24 took placebo (acetic acid diluted with water).

Specific biomarkers for the immune system, inflammation and oxidative status were measured before and after the four-week intervention. The results provide evidence of the immunomodulatory, anti-inflammatory and antioxidant effects of Regulat.

#### Overview of interrelated effects of Regulat demonstrated in a study in human volunteers

#### **Anti-inflammatory effects**

- Cell adhesion molecules \
- hsCRP ↓

#### **Antioxidant effects**

- Reduced glutathione ↑
- Improved total oxidative status

### **Enzyme regulatory effects**

 Improvement of intracellular metabolism

### Immunomodulatory effects

- Apoptosis function (or lytic function) NK cells improved
- Alarm state of neutrophil granulocytes

#### Positive effects on natural killer cells

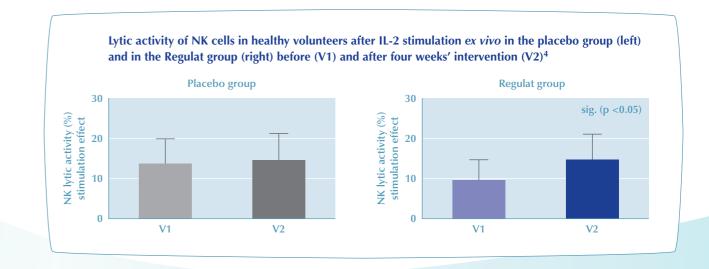
The study focused particular attention on natural killer (NK) cells. These specialised lymphocytes are components of the innate nonspecific immune response and offer the body's first-line of defence against invading pathogens. They bind to foreign cells, releasing enzymes and other substances which damage the membranes of the target cells. In this way, NK cells can eliminate micro-organisms, cancer cells and virus-infected cells. They also produce specific cytokines, which regulate certain functions of T and B lymphocytes, and macrophages.

The study in healthy volunteers examined NK cell function in each person before the start of the study (V1) and after taking Regulat for four weeks (V2). Lytic activity against specific target cells was determined *in vitro*. A slight but not significant increase in the number of lysed cells was seen in both groups at the end of the study. The analysis was then repeated with the addition of interleukin-2 (IL-2), a cytokine that is a potent activator of NK cells. There was a significant increase in the mean stimulated lytic activity compared with baseline without Regulat (V1: 9.7% vs V2: 14.7%, p = 0.027). The increase in the placebo group was only slight (V1: 13.7% vs V2: 14.6%).

### Nonspecific immunity boosted

The significant increase in IL-2-induced lytic activity shows that Regulat helps to increase the cytokine activation necessary for NK cell function. Direct stimulation of NK cells by polyphenol components may be responsible but it may also be attributed to improved cell immunocompetence due to the antioxidant effects of the Regulat, which were also demonstrated in this study. NK cell function is considered to be representative of nonspecific immunity. The improved performance of these cells under Regulat is extremely important for combating virus-infected or malignant cells - and may be considered the foundation of a functional immune system. In contrast, the indiscriminate use of pure immunostimulants (such as mistletoe extract), may lead to the accumulation of nonfunctional cells. Whether this accumulation triggers allergy or autoimmune disease is currently under discussion.

In vitro/ex vivo experiments in which leucocytes from ten volunteer donors were specifically stimulated in the laboratory confirmed that Regulat heightened the alarm state of NK cells.<sup>5</sup> After incubation with small quantities of RechtsRegulat® (dilution of 1:500), 50% of the samples reacted with the release of interferon-gamma (IFN-y).



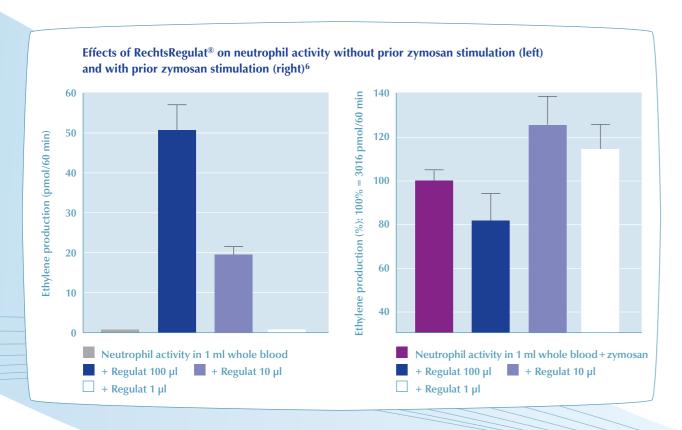
The stimulated cytokine release profile indicated that the IFN- $\gamma$  had come from NK cells (and not from T helper cells, which also produce IFN- $\gamma$ ). Cytokine triggers pro-inflammatory immune reactions, which efficiently eliminate intracellular viruses or bacteria. When testing products of plant origin, it is not unusual for only 50% of the samples to show activation. Interindividual differences in the immunocompetence of cells are considered responsible.

# "Pre-alarm state" of neutrophil granulocytes

Neutrophil granulocytes, another important component of nonspecific immunity, are also favourably influenced by Regulats. *In vitro* tests, carried out at the Freising-Weihenstephan Centre of Life and Food Sciences, Technical University of Munich, have confirmed these effects.<sup>6</sup>

Neutrophils circulate in the blood and penetrate affected tissues during infection/inflammation. They recognise potential pathogens, ingest them (phagocytosis), and destroy them. In the process, they release enzymes and various reactive oxygen species (the "respiratory burst"), including cytotoxic hypochlorous acid (HOCl) which kills the phagocytised bacteria and viruses. HOCl production is catalysed by myeloperoxidase, an enzyme specific to neutrophil granulocytes.

This process can be followed in whole blood in a specific test system. 1-aminocyclopropane-1-carboxylic acid (ACC) is added to the sample as an indicator molecule. The action of HOCl releases ethylene from ACC, and this can be determined by gas chromatography. As previously demonstrated, the addition of RechtsRegulat® increases the formation of ethylene in a concentration-dependent manner (see "Alternating therapy", page 84). This is an expression of HOCl production and in turn, of neutrophil activation. If the sample to be stimulated contains the inflammatory marker zymosan (a yeast cell-wall product), tests show only a very slight increase in ethylene production with 1  $\mu$ l Regulat. Statistically significant stimulation is seen with 10 µl, while significant inhibition of



the activity of neutrophils already stimulated by zymosan is found with 100 µl. This means that Regulats act to induce a "pre-alarm state" in the neutrophils that apparently helps prevent the excessive production of reactive oxygen species.

#### More TNF $\alpha$ secreted on demand

Regulat has also been shown to activate monocytes. Monocytes migrate during infection into tissues, where they develop into macrophages; large phagocytic cells. Low concentrations of tumour necrosis factor alpha (TNF $\alpha$ ), produced particularly by monocytes, serve to regulate inflammatory cells in the tissues. TNF $\alpha$ -initiated expression of adhesion molecules on endothelial cells and the activation of migrated leucocytes result in the release of more cytokines and the accumulation of inflammatory cells at the site of inflammation.

A TNF $\alpha$  response test was also performed as part of the *in vitro/ex vivo* experiments on immunoregulation.<sup>5</sup> It was carried out with the addition of small pre-activating quantities of lipopolysaccharide (LPS) from the outer membrane of Gram-negative bacteria. LPS acts as an endotoxin and provokes immune reactions. In all samples, incubation with added Rechts-Regulat<sup>®</sup> (1:500) showed an increase in TNF $\alpha$  secretion; an indicator of monocyte activation.

### Antibacterial and antimycotic effects

Regulat can also directly render pathogens such as bacteria and fungi harmless. This has been suggested by a microbiological challenge test conducted in a biochemistry laboratory. The RechtsRegulat sample supplied for the test was germ-free, as confirmed by subcultures on broad-spectrum nutrient agar tubes. The Regulat was then inoculated with a mixed suspension of micro-organisms, in concentrations of about 10<sup>5</sup> to 10<sup>6</sup> micro-organisms per ml. The sample was incubated at a temperature of 25°C throughout the test and the micro-organism count checked by subcultures set up at different times.

#### Micro-organisms used

#### **Bacteria**

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Escherichia coli
- Proteus mirabilis
- Enterobacter gergoviae

#### **Yeasts and moulds**

- · Aspergillus niger
- Penicillium expansum
- Trichoderma viride
- Candida albicans

#### **Results**

The challenge test with the standard organisms (a selection of typical environmental organisms), showed very good biological stability in comparison with the single weak challenge. The added organisms were undetectable within two days and the Regulat sample was once again germ-free. There were no microbe-induced macroscopic changes during the course of the test.

#### In summary

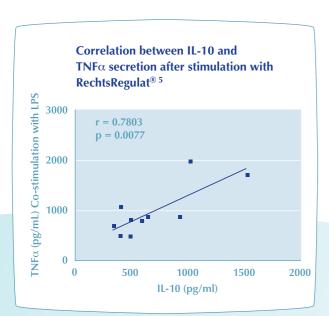
- With its high content of different polyphenols and probiotic cell wall fragments, Regulat activates the nonspecific immune system.
- Regulats enhance the functions of natural killer cells and neutrophils.
- The microbiological challenge test has shown antibacterial and antimycotic effects of Regulats.
- Regulat supports the ideal combination of "healthy" gastrointestinal flora.

# **Anti-inflammatory and antiallergic effects**

Inflammation defends the body from attacks of various kinds. It sets in motion a highly complex chain reaction, in which white blood cells have a pivotal role. They facilitate the immune response by releasing cytotoxic and proinflammatory messengers and reactive oxygen species, in addition to their phagocytic properties. Pathogens and noxious substances that have entered the body are rendered harmless. However, excessive inflammatory reactions or chronic "silent" inflammation are responsible for many health problems. Many age-related diseases and possibly ageing itself may now be considered a result of inflammation.

#### Interleukin-10 secretion stimulated

Excessive TNFα reactions within the inflammatory process are inhibited by interleukin-10 (IL-10). This anti-inflammatory cytokine has a key role in limiting and terminating in-

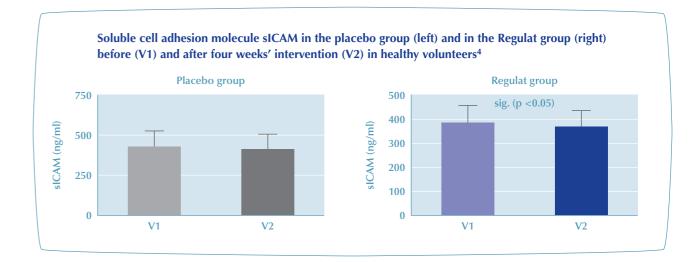


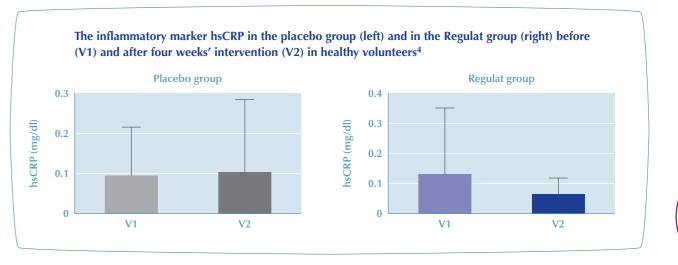
flammatory reactions and in the development of immune tolerance. The in vitro/ex vivo experiments on immunoregulation under the influence of RechtsRegulat® showed a clear stimulation of monocytic IL-10 secretion in all healthy volunteers.<sup>5</sup> Regulats induce a high alarm state in monocytes, activating not only pro-inflammatory processes (to combat infection) but also anti-inflammatory processes (to prevent excessive reactions). In addition, a cortisone-like effect on skin cells has been demonstrated (see page 56).11

#### Cell adhesion molecules reduced

Adhesion of circulating white blood cells to the vascular endothelial layer is essential for migration into tissues to defend against noxious substances, and in the pathogenesis of inflammatory disease. Cell adhesion molecules are responsible and these include:

- Vascular cell adhesion molecule 1 (VCAM-1), which promotes the adhesion of lymphocytes, monocytes, NK cells, eosinophil and basophil granulocytes to endothelial cells.
- Intercellular adhesion molecule 1 (ICAM-1), which is always present in low concentrations in membranes and endothelial cells, but which increases greatly when stimulated by pro-inflammatory cytokines such as IL-1 and TNFα. High concentrations of the soluble form (sICAM-1) are found in the blood in various inflammatory diseases such as arteriosclerosis, rheumatoid arthritis, psoriasis and the metabolic syndrome.





The soluble forms of adhesion molecule, sl-CAM-1 and sVCAM-1, are important biomarkers for inflammatory processes associated with activation or damage to cells such as platelets or endothelium. In the study on healthy volunteers, there was a significant reduction in plasma sl-CAM-1 (p = 0.0119) and s-VCAM (p = 0.0020) after taking Regulat for four weeks, but not in the placebo group.4

The analysis of the nonspecific inflammatory marker C-reactive protein also highlights the anti-inflammatory effects of Regulats. Levels of highly sensitive C-reactive protein (hsCRP) fell considerably on RechtsRegulat®.

#### Earlier intervention in the inflammatory cascade

These results are all the more surprising as all the volunteers were healthy and most of them had a baseline CRP within normal limits (<0.5 mg/dl). Even greater improvement is to be expected with Regulat in patients with chronic inflammatory disease. Unlike non-steroidal anti-inflammatory drugs, for example, the anti-inflammatory effects of Regulat are seen very early in the inflammatory cascade. Cell adhesion is one of the first steps in the development of inflammation.

How does Regulat work? 45

# Cytokine results indicate protection against allergy

Regulat does not directly affect specific immunity. The in vitro/ex vivo experiments did not find evidence of increased interleukin-4 (IL-4) secretion. This cytokine is released by Th2 cells after antigen presentation. In this way, T helper cells promote the differentiation of B lymphocytes into plasma cells and stimulate antibody production. Increased IL-4 synthesis triggers an excessive Th2 immune response and frequently occurs in atopic individuals and certain autoimmune diseases. The fact that RechtsRegulat® does not induce IL-4 secretion is to be viewed positively: it does not reinforce atopy or allergic reactions. The increase in IL-10 secretion demonstrated when taking Regulat also indicates protection against allergies. IL-10 is important in the development of immune tolerance and helps prevent excessive immune reactions.

#### **Probiotic potential of Regulat**

Activation of immune cells in the intestinal tract and blood does not require probiotic yoghurts with live lactic acid bacilli capable of reproducing, pure cultures of Gram-positive organisms or bacterial preparations – cell wall structures are enough. Regulat from fruit and vegetables contains a high proportion of cell wall components with probiotic effects from

the fermentation cultures, the peptidoglycans and lipoteichoic acids with immune properties. In fact, lactic acid fermentation products of plant origin also affect immune reactions to that effect, strengthening immune defences and adapting the immune status so that there are fewer "excessive reactions" that may trigger inflammation and allergies.

Various studies have shown that taking lactobacilli may have antiallergic effects. In children, the composition of the intestinal flora correlates directly with their allergy risk. More *Clostridia* spp. and fewer bifidobacteria and lactobacilli were found in young patients with atopic dermatitis than in children without. And if pregnant women were given lactobacilli two to four weeks before the expected date of delivery, the risk of atopic dermatitis in their children was halved. This protection lasted up to four years. By inducing intestinal tract immunity, early probiotic therapy can reduce the occurrence of food allergies and thus ensure oral tolerance.

#### **In summary**

- Inflammatory processes have a key role in many diseases. Even ageing is now viewed as an inflammatory process.
- Regulat suppresses excessive proinflammatory activity.
- Non-interventional studies of Regulat have shown marked protection against various allergies.

#### **Detoxification/deacidification**

Our exposure to foreign substances with potential toxic effects is ever-increasing. Potential xenobiotics (from the Greek: *xenos* = foreign, *bios* = life) include:

- Food additives such as stabilisers, preservatives, colourings
- Pesticide and fertiliser residues
- Products from denaturising manufacturing processes, early cropping or long storage
- Medication

Substances that are readily water soluble can be excreted directly via the intestinal and urinary tracts or exhaled from the lungs. Our bodies have developed an enzymatic system to detoxify and excrete lipophilic (poorly water soluble) substances which are often toxic. This system consists of two phases:

# Phase I – oxidation of lipophilic substances

The cytochrome P450 (CYP450) metabolising system exists for the oxidation of compounds that are not readily metabolised. It oxidises fat-soluble compounds with the help of a haem iron catalyst (pigment 450). Oxidation of aromatic compounds primarily produces epoxides, where one oxygen atom is bound to two adjacent carbon atoms. Some of these epoxides are highly reactive; they may be deposited on genetic material and cause mutations. Epoxide hydrolases split the epoxides into two hydroxyl groups, forming more readily water-soluble and usually harmless diphenols.

CYP450 hydroxylases and mono-oxygenases are the most important phase I enzymes. In each case, they are induced by an appropriate substrate. The problem, however, is that every enzyme induction represents oxygen activation and may result in oxidative stress.

# Phase II – formation of derivatives by transferases and their subsequent excretion

In phase II of detoxification, various enzyme groups work together to convert previously water-insoluble xenobiotics to an excretable form. In principle, this involves conjugating the highly reactive hydroxylation product from phase I with a readily water-soluble molecule (for example, glucose, glutathione or sulphate) to facilitate its excretion via the kidneys. One key phase II enzyme group consists of sulfotransferases. They transfer a sulphate residue from an energy-rich donor (3'-phosphoadeno-sine-5'-phosphosulphate, PAPS) to an oxidised recipient (the xenobiotic rendered highly reactive by hydroxylation):

Xenobiotic + PAPS → Sulphated xenobiotic + PAP

The sulphated xenobiotic can now be excreted. This process is not without cost; synthesis of PAPS (also known as activated sulphate) requires metabolic energy in the form of ATP.

#### Phenolic acids induce detoxification enzymes

Chinese scientists have published interesting details about the induction of phase II enzymes such as sulfotransferases, especially the subgroup of phenylsulfotransferases.<sup>8</sup> Investigating phenol sulfotransferase induction in HepG2 cells (a cell line with all the main properties of detoxified liver cells), they found that these detoxification enzymes are induced by phytochemicals, in particular, by certain simple phenolic acids. They also found that the more concentrated the phytochemicals in the vegetable preparation were, the more enzyme was induced. Enzyme induction correlated positively with the antioxidant capacity of the vegetable preparation and its phenol count, measured by the Folin-Ciocalteu method. Individual phenolic acids, such as gallic acid, act synergistically in the induction.

Regulat reinforces detoxification in the body. It contains high concentrations of phenolic acids responsible for the synergistic effects in inducing phenol sulfotransferases in liver cells reported by Yeh and Yen<sup>8</sup>. In particular, simple hydroxylated phenolic acids such as gallic acid, para-hydroxybenzoic acid and para-coumaric acid derivatives. According to Prof. Erich F. Elstner, formerly Professor of Phytopathology at the Freising-Weihenstephan Centre of Life and Food Sciences, Technical University of Munich, more than 500 different phenolic substances, mostly antioxidants, have been identified in RechtsRegulat®. The Lactobacillus cell wall material present also has a role in detoxification as it may bind potential toxins and cause them to be excreted.

#### Reduced glutathione for the liver

The detoxification of xenobiotics relies heavily on reduced glutathione (GSH). During phase II hepatic detoxification, the formation of glutathione conjugates ensures that toxins and other substances can be eliminated via the kidneys. In addition, reduced glutathione has substantial detoxifying effects on the liver parenchyma. In the human study described, there was a significant rise in reduced GSH in all cells examined (lymphocytes, monocytes, NK cells) after intake of RechtsRegulat® over four weeks.4 This is an important finding as reduced glutathione is extremely labile and rapidly oxidised into an inactive form in the presence of oxygen or gastric acid. It can therefore be assumed that more reduced GSH is present in all cells of people taking Regulats. This increase in the intracellular concentration of reduced glutathione may explain some of the very positive effects of the cascade-fermented bioconcentrates on metabolism.

#### Improved liver and kidney function

Improved excretion via the liver and kidneys has been observed in practice. An open-label study including obese patients and people with diabetes found improved uric acid, creatinine and electrolyte concentrations after intake of Regulats (10 ml Regulat Special Diet, mornings and evenings) over six months. This is evidence of improved excretory kidney function.<sup>9</sup> Improved hepatic function was reflected by considerably lower levels of the liver enzymes gamma-glutamyltransferase (yGT) and alanine aminotransferase (ALT).



#### Acid-base balance regulated

Regulat undergoes basic (alkaline) metabolism. They may result in profound deacidification of the body. This process is not based on transient buffering of acids by the addition of basic components. Instead, fundamental enzyme feedback loops regulate the acid-base balance by natural means.

Regulat also reduces oxidative/nitrosative stress. It is a potent antioxidant and increases the reduced glutathione in cells, as has been confirmed by various studies. Consequently, no acid is produced in the tissues.

#### **In summary**

- Hydroxylated phenolic acids, such as those found in high concentrations in Regulat, promote detoxification in the liver by inducing phase II metabolising
- In practice, improved excretory liver and kidney function has been demonstrated on intake of Regulat.
- Regulat ensures a natural regulation of the acid-base balance.

#### **Antioxidant effects**

Antioxidants protect the body from the negative effects of reactive oxygen species. This is important for cell membranes with their numerous unsaturated fatty acids, the double bonds of which are readily oxidised, resulting in impaired function. All metabolic enzymes can be damaged and rendered useless by ROS. Antioxidants help to maintain metabolic homeostasis.

Regulat contains many secondary plant metabolites which are natural antioxidants. An analysis carried out by Prof. Elstner's research team at the Freising-Weihenstephan Centre of Life and Food Sciences, Technical University of Munich, found a high concentration of phenols: 3 mM as measured by the Folin-Ciocalteu method.<sup>6</sup> The total phenol content was 164 µg/ml: simple acids 14.97 µg/ml, hydroxycinnamic acid 0.24 μg/ml, flavanones 83.80 μg/ml, flavones 21.38 μg/ml, still unidentified phenols 43.59 μg/ml. Bile acid and 4-hydroxybenzoic acid were the most common simple phenols, accounting for 4.8 μg/ml and 6.23 μg/ml, respectively.

#### Potent antioxidant in oxidative stress models

The antioxidant potential of Regulat has been tested in various biochemical reaction models in which oxidative stress reactions as seen in various disease processes were simulated.<sup>10</sup> The models consist primarily of an activation reaction in which ROS are produced, and an indicator molecule which reacts sensitively with the ROS to give a signal that can be measured. Models used included:

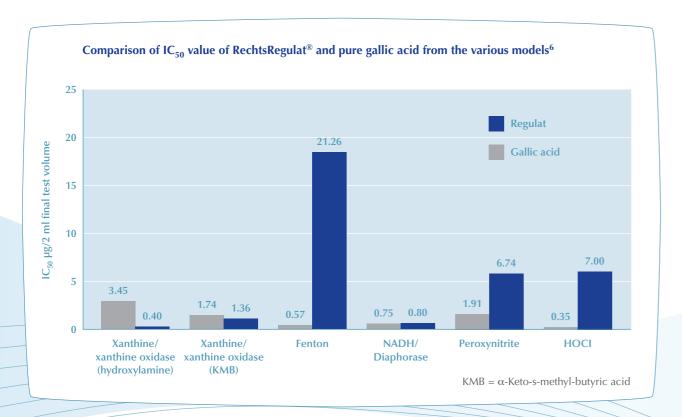
- Xanthine/xanthine oxidase model (with hydroxylamine and S-methyl-alphaketobutyric acid (KMB) as the indicator)
- Fenton reaction
- NADH/diaphorase system
- Reaction with peroxynitrite
- Reaction with HOCl

To rate the efficacy of RechtsRegulat®, gallic acid and salicylic acid were used as reference substances in the study. The  $IC_{50}$  (the concentration of test substance which causes 50% inhibition of the model system) was calculated.

#### Disease-related biochemical model systems **Product** Disease, symptom **Key enzyme Target system** O<sub>2</sub>-, OH• DNA, fats Gout, ischaemia Xanthine oxidase Membranes Perfusion Fenton chemistry O<sub>2</sub>-, OH• Oxidoreductases Proteins, DNA Poisoning Chemotherapy Diaphorases Semiquinone Fats side effects Fenton chemistry Inflammation Myeloperoxidase HOCI Unsaturated fats Vitamins Nonspecific immune reaction Singleton O<sub>2</sub> Vascular damage NO-synthase Peroxynitrite **Proteins** Oxidoreductases Membranes DNA = deoxyribonucleic acids modified from Elstner EF. Enzym- und Immunmodulation: die neue Gesundheitsvorsorge [Enzyme modulation and immunomodulation: innovative healthcare]. Stuttgart 2008

In the study, RechtsRegulat<sup>®</sup> demonstrated marked antioxidant properties, which were measured against those of pure gallic acid. Gallic acid is a key substance in the phenol group to which excellent antioxidant properties have been ascribed. Regulat performed considerably

better on average than pure gallic acid in the Fenton system (OH radicals are not generated enzymatically by the reaction of hydrogen peroxide with Fe<sup>2+</sup>), as well as against the aggressive oxygen and nitrogen species hypochlorous acid (HOCl) and peroxynitrite.

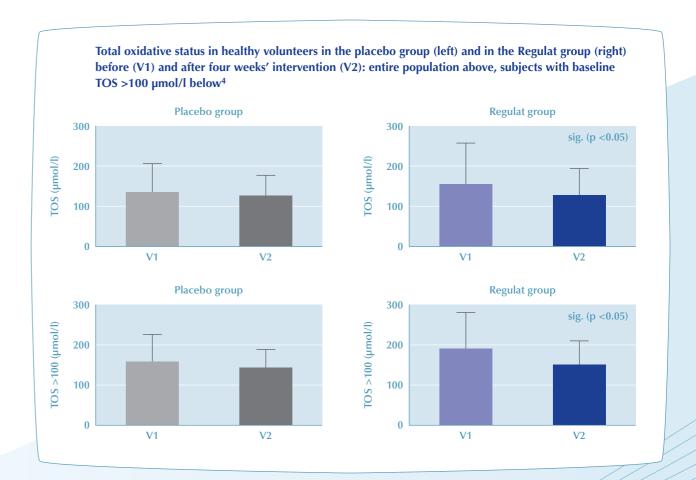


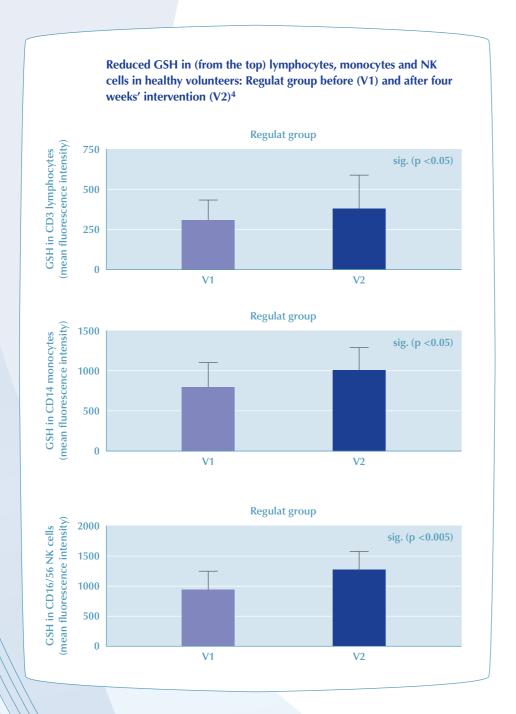
#### Improved total oxidative status

An imbalance between reactive oxygen species and antioxidants causes oxidative stress. As a result, unsaturated fatty acids are oxidised to lipid peroxides. These lipid peroxides are a well-known marker of oxidative stress in biological fluids. A commercial test kit allows the lipid peroxides in plasma and hence the total oxidative status (TOS) to be determined easily and quickly by a colorimetric method.

Regulat significantly improves an unfavourable oxidative status, as demonstrated by TOS analyses in the randomised double-blind placebo-controlled trial of RechtsRegulat®.4 The baseline values of the healthy volunteers were

comparably low (a mean of 135.7 µmol/l  $H_2O_2$  equivalents in the placebo group and 155 µmol/l in the Regulat group). After four weeks' intervention, the values on Regulat had improved by a mean of –26.2 µmol/l (p = 0.0519) but only by –10.1 µmol/l in the placebo group. A subgroup analysis of subjects with higher baseline TOS values (>100 µmol/l) showed a significant fall of –39.5 µmol/l (p = 0.024) in the Regulat group but of only –16.1 µmol/l in the placebo group, which was not statistically significant. Once again RechtsRegulat® was shown to be a true regulator; the oxidative stress was reduced to a greater extent in those individuals with higher baseline values.





# Increase in reduced glutathione in the cells

The most important cell protection system against oxygen radicals and other reactive species is reduced glutathione (GSH). With the help of the enzyme glutathione peroxidase, hydrogen is transferred from glutathione to the ROS, for example, hydrogen peroxide, rendering it harmless and thus maintaining normal cell function. With intake of RechtsRegulat® over four weeks in the human study, the intracellular concentration of reduced GSH rose significantly in all cells investigated, namely lymphocytes, monocytes and NK cells, while only marginal effects were seen with placebo.<sup>4</sup>

An improved GSH supply in the cells due to Regulats has also been observed in practice, for example, in a prospective study of effectiveness under real-life conditions which included mainly patients with weight problems, metabolic syndrome or type-2 diabetes.<sup>2</sup> The intracellular concentration of reduced GSH was determined in four patients. With intake of Regulats (10 ml RegulatPro® Metabolic, morning and evening), values increased by +118.3% in the lymphocytes, by +17.6% in the monocytes and by +26.1% in the NK cells.

It was also encouraging that nitrotyrosine levels fell by a mean of 43.6% in this study. This biomarker of nitrosative stress arises from the deposition of peroxynitrite on the amino acid tyrosine. It correlates directly with the much-feared undesirable production of peroxynitrite. This reactive nitrogen species is a strong oxidant; it may cause a chronic energy deficit by inhibiting mitochondrial enzymes and also considerable metabolic dysfunction because of its high affinity to aromatic amino acids.

#### **In summary**

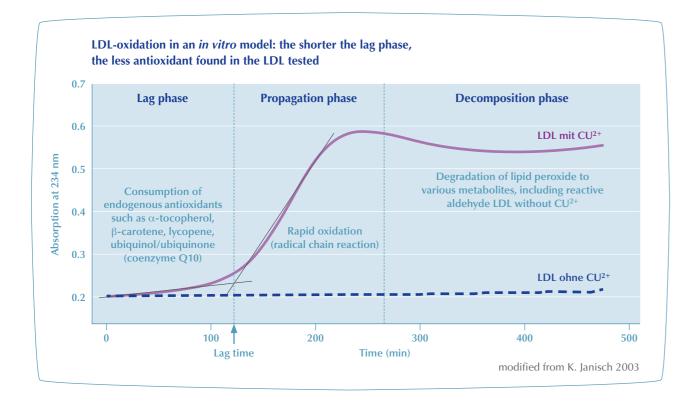
- Regulat contains a wide range of natural antioxidants.
- The antioxidant potential of Regulat has been confirmed both *in vitro* and *in vivo*.
- Regulat leads to a considerable increase in reduced glutathione in the cells – providing excellent intracellular protection against oxidative stress.

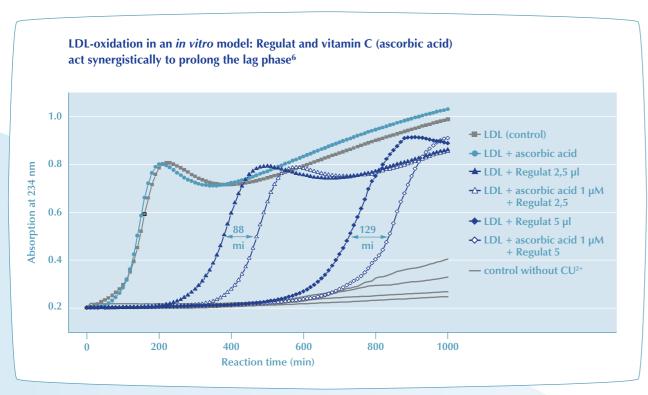
#### **Antiarteriosclerotic effects**

Low-density lipoprotein (LDL) cholesterol – "bad" cholesterol – is one of the most important cardiovascular risk factors. Oxidation of LDL is deemed to be the initial process in arteriosclerotic changes. Numerous studies have demonstrated that oxidised LDL cholesterol has atherogenic effects and increases the risk of a heart attack.

LDL is a lipoprotein particle, consisting of phospholipids, apolipoprotein B and various

antioxidants. It has the task of binding cholesterol from peripheral blood and transporting it into cells. Macrophages in the blood engulf it in a controlled manner via specific LDL receptors. The uptake of oxidized LDL particles, on the other hand, is via unregulated scavenger receptors and therefore is not limited, allowing the macrophages to "overeat". In addition, it triggers the invasion of these lipid-laden foam cells into the vascular endothelium, forming fatty streaks and ultimately atheroma.





LDL, which has a strongly hydrophobic core containing cholesterol esters (with linoleic acid being the most prevalent fatty acid), is highly susceptible to oxidation. Despite the incorporated antioxidants (especially  $\alpha$ -tocopherol, carotenoids and reduced coenzyme Q10) the body's natural systems, transition metals such as Fe<sup>2+</sup> and ROS can trigger the oxidation of LDL. Oxidation induced by Cu<sup>2+</sup> is now used as an in vitro model to test the effects of antioxidants on LDL oxidation resistance. If an LDL sample is examined in a quartz cuvette in a spectrophotometer, LDL oxidation can be determined about 120 minutes after the addition of a minute quantity of a copper salt by measuring the increase in light absorption at 234 nm in the ultraviolet range. LDL oxidation depends on the formation of conjugated dienes which arise as a result of fatty acid peroxidation. The lag time before oxidation starts is an expression of the protection afforded by intrinsic antioxidants in the LDL particles.

# Reduction of LDL oxidation and its serious consequences

Regulat stabilises LDLs against oxidation. Studies carried out at the Freising-Weihenstephan Centre of Life and Food Sciences, Technical University of Munich, showed that the onset of oxidation clearly depended on the quantity of RechtsRegulat® added. The lag time increased by 220 minutes (to 344 minutes in total) with the addition of 2.5  $\mu$ l, and by 560 minutes (to 676 minutes) with 5  $\mu$ l. These results suggest that LDL could resist oxidation by copper ions for very much longer in the presence of Regulat.

# Time until LDL-oxidation in an *in vitro* model

No additions 120 min

+ Vitamin C 108 min

+ Regulat 344 min

+ Vitamin C and Regulat 432 min

The other test results are particularly interesting: the addition of vitamin C (ascorbic acid, 1 µM) alone slightly accelerated the onset of LDL oxidation by 12 minutes (to 108 min), which can be attributed to the reduction of Cu²+ to Cu+ by ascorbic acid. The simultaneous addition of vitamin C (1 µM) and RechtsRegulat® (2.5 µg), however, prolonged the lag time to 432 minutes. Vitamin C apparently works synergistically with the phenolic components of Regulat and enhances the protection against oxidative damage of LDL. The interaction of Regulats and vitamin C develops synergistically, his cooperation is extremely relevant in the prophylaxis against heart attacks.

#### In summary

- Oxidised LDL cholesterol sets the development of arteriosclerosis in motion.
- Regulat makes LDL much more stable to oxidation.
- Working together, Regulat and vitamin C provide strong protection; 10 ml of Regulat prolongs the lag phase to 10 hours.
- Vitamin C alone has a pro-oxidative action.



# How does Regulat affect the body? Overview of the indications

Cardiology		Musculoskeletal system	
Hypertension	47	Rheumatoid arthritis/osteoarthritis	63
Arteriosclerosis	49	Gout	64
A A A TOTAL TO THE		Fibromyalgia	65
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Metabolic syndrome	51	ENT	
Hyperlipidaemia	51	Sinusitis	67
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Allergies	55	Dietary deficiency	71
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Disorders of wound healing	57	Mental health	
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#### **Overview of the indications**



# Cardiology

### **Hypertension**

High blood pressure is one of the main cardiovascular risk factors. Untreated or inadequately treated hypertension increases the risk of cardiac insufficiency, myocardial infarction and sudden cardiac death, renal failure and stroke. Most cases are of essential hypertension, when no specific underlying cause, such as kidney disease, can be found for the high blood pressure. Obesity, a sedentary lifestyle, stress, smoking, excessive alcohol consumption, and a high-salt diet may all contribute to high blood pressure in a genetically predisposed individual. Arteriosclerosis impairs the natural regulation of the blood pressure and the risk of hypertension increases. Blood vessels with arteriosclerotic changes, which are no longer very elastic, can only dilate and constrict with difficulty.

#### How Regulat helps

- A supply of valuable building blocks for enzyme synthesis, as well as numerous phytochemicals helps to regulate the blood
- The body has a better energy supply, which is experienced subjectively by feeling more energetic and able to do things.
- Oxidative stress (which leads to the development of arteriosclerosis and its consequences) is reduced.
- The production of oxidised LDL cholesterol, a dangerous risk factor because of its atherogenic effects, is diminished.
- The vascular walls regain their elasticity, arteriosclerotic deposits are broken down. The metabolism and excretion of toxins that have accumulated in the body also function better.
- The stimulation of metabolism in overweight people leads to weight loss, which in turn contributes towards preventing cardiovascular disease.

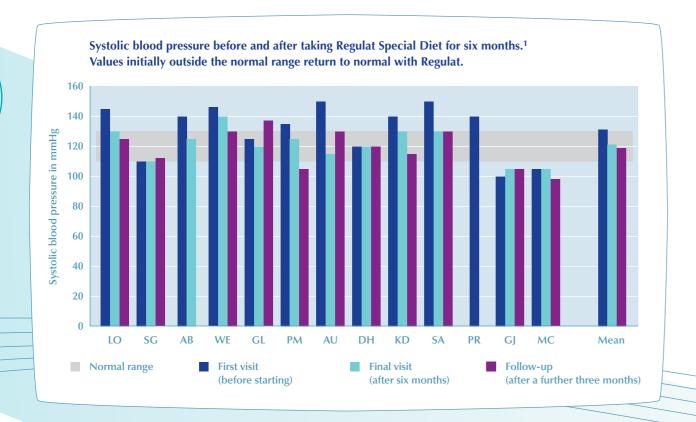


# Study data of interest

Several studies in complementary and alternative medical (CAM) practices have confirmed that high blood pressure is lowered when taking Regulat. In an open-label study, 13 patients, some of whom were obese or had diabetes, took Regulat Special Diet (10 ml, morning and evening) for six months. 1 During this time, the mean systolic blood pressure fell from 131 mmHg to 121 mmHg; the diastolic pressure from 74 mmHg to 69 mmHg. This blood pressure-lowering effect is comparable to that of moderate sporting activity, for example, walking for 20 minutes three times a week. It was also gratifying that the patients lost weight - 4.6 kg on average. Results of the questionnaire showed participants felt more energetic and able to do things by 55% on average and concentration improved by 43%.

Another study, in which participants took RegulatPro® Metabolic (10 ml, morning and evening) for six months, found a clear reduction in blood pressure.<sup>2</sup> Seven of the 15 subjects had diabetes mellitus while six had confirmed metabolic syndrome; ten of them were obese. On taking Regulat, the mean systolic blood pressure decreased from 140 mmHg to 124 mmHg; the diastolic pressure was reduced from 82 mmHg to 77 mmHg. The blood pressure increased again slightly in the following three months without Regulat to a mean of 127/78 mmHg. The pulse rate (baseline mean: 72 beats/min) became more efficient (61 beats/min after six months and 64 beats/min after nine months). Although patients made no changes to their diets during the time they were taking Regulat, they weighed less (mean 4.5 kg) after nine months. They also felt subjectively better, with more energy to do things (+53%) and improved concentration (+58%).

Blood pressure was also reduced slightly in a third study with RechtsRegulat® (10 ml, morning and evening) over three months, although the baseline values were already satisfactory in almost all 31 participants.3 All of them had a chronic lack of energy. As shown by the ATP content of the granulocytes, taking Regulat for three months resulted in a highly significant increase in ATP, with levels returning to normal.



The patients also reported clearly improved well-being with greater physical fitness (+60%) and better ability to concentrate (+59%).

Levels of vanillylmandelic acid (VMA), the main metabolite of adrenaline and noradrenaline (the catecholamines which cause blood pressure to rise), returned to normal in nearly all participants. This finding suggests that a previous stress-induced increase in sympathetic nervous activity could be reduced. Levels of homovanillylmandelic acid, metabolite of the catecholamines dopa and dopamine, also decreased. This may indicate that Regulats have a regulatory function in dopamine metabolism, leading to reduced excitability.

#### **Arteriosclerosis**

Arteriosclerosis is the deposition of fatty substances in the arterial walls resulting in the development of atheroma or arteriosclerotic plaques. The vessel walls become thickened and lose their elasticity; blood flow is at first impeded and then finally obstructed. Apart from familial predisposition and age, there are many modifiable risk factors for arteriosclerosis, including smoking, high cholesterol levels, hypertension, diabetes mellitus, overweight and a lack of exercise. Oxidative stress appears to be causative in the development of arteriosclerosis: oxidation of LDL cholesterol is deemed to be an initial process in arteriosclerotic changes. Inflammation, infections and immune reactions also seem to play a part. Diseases arising from arteriosclerosis are the most common cause of death in most Western countries. They include heart attacks and strokes, but also renal failure and intermittent claudication (peripheral artery occlusive disease) due to narrowing of the leg arteries.

#### How Regulat helps

- It reduces oxidative stress, which favours the development of arteriosclerosis.
- The oxidation resistance of low-density lipoprotein increases, so that less oxidised and atherogenic LDL cholesterol is formed.
- There is a synergistic action with other antioxidants, such as vitamin C.
- The established anti-inflammatory effects may also contribute to vascular protection.
- · Regulatory effects on carbohydrates, fat and energy metabolism, as well as blood pressure, help to combat cardiovascular risk factors - important not only in primary prevention, but also to arrest the progression of vascular changes.
- Vessel walls regain their elasticity; arteriosclerotic deposits are broken down.

#### Study data of interest

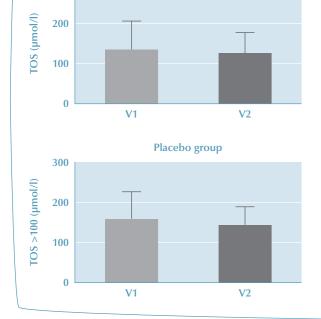
The antioxidant potential of Regulat is of particular interest in this respect. Regulat contains various secondary plant metabolites (phytochemicals), especially polyphenols that function as natural antioxidants. The oxidation protection from Regulat has been confirmed in a randomised, double-blind, placebo-controlled trial on 48 healthy men who took RechtsRegulat® (10 ml, morning and evening) or placebo for four weeks.<sup>4</sup> The plasma total oxidative status (TOS) was determined at baselines and following treatment.

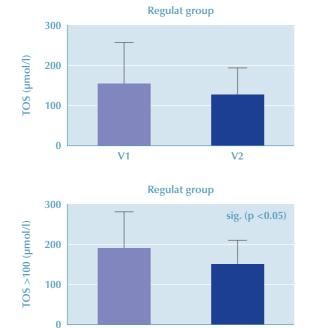
Arteriosclerosis: vessel wall with plaque formation



Placebo group

#### Total oxidative status in healthy volunteers in the placebo group (left) and in the Regulat group (right) before (V1) and after four weeks' intervention (V2): entire population above, subjects with baseline TOS >100 µmol/l below4





Although baseline values in the healthy volunteers were comparatively low, after four weeks' intervention they had still clearly improved in the Regulat group but hardly at all in the placebo group. The improvement of -39.5 µmol/l in subjects with higher baseline TOS values (>100 µmol/l) was significant, but the fall of −16.1 µmol/l in the placebo group was not. Regulat is therefore a true regulator: oxidative stress is reduced to a greater extent in patients who have higher baseline values.

The antioxidant effects were also reflected in a significant increase in intracellular levels of reduced glutathione (GSH), the most important cell protection system against oxidative stress. An effectiveness study (under real-life conditions) showed a clearly improved intracellular supply of GSH when taking Regulats.<sup>2</sup> As demonstrated by the Freising-Weihenstephan Centre of Life and Food Sciences, Technical

University of Munich, Regulat protects against LDL oxidation.<sup>6</sup> An *in vitro* model showed that the onset of LDL oxidation was considerably delayed by the addition of RechtsRegulat®; the combined addition of Regulat and vitamin C prolonged this time even further. Regulats and vitamin C therefore have a synergistic action in protecting LDL cholesterol from oxidation and prolonging the lag phase to ten hours.

#### Time until LDL oxidation in an in vitro model Without additions 120 min + Vitamin C 108 min + Regulat 344 min + Vitamin C and Regulat 432 min

# Metabolic disorders

#### **Diabetes mellitus**

Raised blood glucose levels are a diagnostic feature of diabetes mellitus, "high blood sugar". The hormone insulin, produced in the pancreas, is insufficient to bring the glucose into cells and make it available for energy production - glucose levels in the blood therefore rise. The most common disease is type-2 diabetes (formerly known as mature-onset diabetes), which occurs mainly in overweight people and is characterised by an increasing insulin resistance of pancreatic islet cells. However, in type-1 diabetes (formerly called juvenile diabetes), the insulinproducing cells of the pancreas are damaged. Without adequate treatment, diabetes may have serious consequences, including increased risk of injury to both small and large blood vessels.



### **Metabolic syndrome**

The "fatal four", as the metabolic syndrome is called because of the possible consequences, consist of abdominal (central) obesity, high blood pressure, altered blood lipids, and insulin resistance. Above all, the metabolic syndrome is the result of an unhealthy lifestyle

with too many calories in the diet and a lack of exercise. Without any effort to overcome these changes, people are at high risk of cardiovascular disease, diabetes and other major health consequences.

### Hyperlipidaemia

Hyperlipidaemia is characterised by elevated cholesterol and/or triglyceride levels. LDL cholesterol (or "bad" cholesterol) levels in particular rise with age and increase the risk of arteriosclerosis. In contrast, high HDL cholesterol (or "good" cholesterol) levels are viewed as favourable. Inherited factors, obesity, a fatand cholesterol-rich diet, lack of exercise and high alcohol consumption, as well as certain diseases, increase the lipid levels. A diet rich in fruit, vegetables and grains is important in combating hyperlipidaemia.

### **Obesity**

Overweight occurs if more calories are consumed than are used. Too much fat then accumulates in the body. The body mass index (BMI) is calculated as weight [kg]/height [m2]. A BMI of 25 is considered to be overweight, and of 30 or more is obesity. Lack of exercise, a fat- and calorie-rich diet, and too much alcohol are important causes. Above all, abdominal (central) fat, which has endocrine effects, is considered dangerous and associated with a higher risk of coronary artery disease, stroke, hypertension, type-2 diabetes and hyperlipidaemia. Weight loss greatly reduces these risks.

#### **How Regulat helps**

Whether for type-2 diabetes, metabolic syndrome, hyperlipidaemia or obesity – thanks to their enzyme regulatory properties, Regulats are extremely helpful in all of these closely interrelated metabolic conditions:

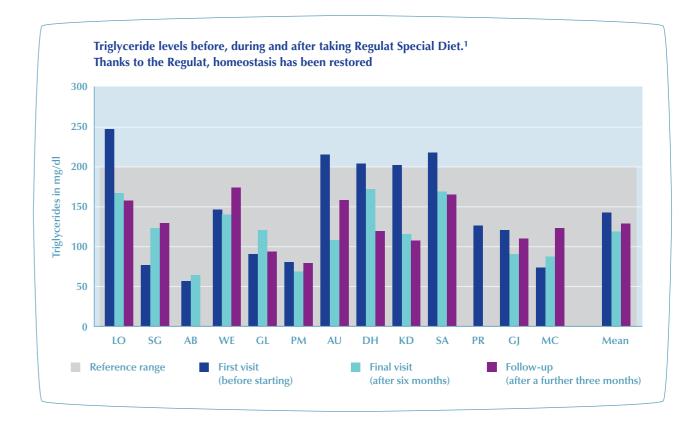
- Metabolic regulation leads to weight loss in overweight/obese people, even if they do not change their previous dietary habits.
- Regulat improves the overall metabolic situation: glucose metabolism (HbA<sub>1c</sub> lowered), fat metabolism (triglycerides and LDL cholesterol lowered, HDL cholesterol raised), energy metabolism (more intracellular ATP) and purine metabolism (uric acid lowered).
- It lowers blood pressure.
- Energy, motivation and concentration increase considerably.

- The antioxidant and anti-inflammatory properties of Regulat, which counteract the development of arteriosclerosis, are of particular relevance to these metabolic problems.
- Regulat also supports the immune defences.

#### Study data of interest

Two prospective studies in a CAM practice confirmed the regulatory and stabilising effects of Regulat taken as daily nutritional supplement in patients with metabolic problems. The first study included 13 patients with type-2 diabetes and/or metabolic syndrome. Taking Regulat Special Diet (10 ml, morning and evening) their metabolism improved considerably within six months. The mean levels of blood glucose, HbA<sub>1c</sub>, insulin, LDL cholesterol, triglycerides, uric acid and homocysteine fell, as did blood pressure and body weight (–4.6 kg). Practically all the laboratory parameters returned to the





normal range or remained normal. Symptoms resolved: patients felt more energetic, were able to concentrate better and had less appetite for sweet foods. At follow-up three months later, the positive trend had reversed in the nine patients who had stopped taking Regulat.

In the second study, 15 people with diabetes or metabolic syndrome took RegulatPro® Metabolic, 10 ml morning and evening for six months.<sup>2</sup> This study also showed a mean weight loss of 4.5 kg even though no dietary changes were made. Blood glucose, HbA<sub>1c</sub> and especially the intact pro-insulin values indicated an improved metabolic profile. The vessel-damaging LDL cholesterol fell from a mean of 130 mg/dl to 114 mg/dl. Analysis of intracellular ATP, which was performed in four patients, showed



a clear increase in cellular energy supply. Reduced glutathione, which protects the cells from oxidative stress, was considerably raised. Participants in this study also reported better subjective findings. 54 Overview of the indications 55

#### **Tailor-made Regulats**

Taking Regulat as a nutritional supplement helps with metabolic problems, as highlighted by the study data.

- There is a cascade-fermented bioconcentrate enriched with bitter melon, B vitamins and trace elements (Regulat Special Diet) for people with diabetes or reduced glucose tolerance. Bitter melon has a beneficial effect on glucose metabolism, as do the trace elements zinc and chrome; they enhance the effects of insulin and lower blood glucose levels. B vitamins boost energy metabolism and protect nerve structure and function, which are often damaged by long-term diabetes.
- If there is evidence of metabolic syndrome, a Regulat with additional vitamins (B vitamins, vitamin C and vitamin D), magnesium and the trace elements chromium, zinc and manganese (RegulatPro® Metabolic) is recommended. Chrome and zinc have beneficial effects on glucose metabolism. Magnesium, manganese, B vitamins, and vitamin C are important for energy metabolism; vitamin B<sub>6</sub> and zinc contribute to normal protein metabolism. Vitamins B<sub>6</sub>, B<sub>12</sub>, C, D<sub>3</sub>, and zinc support normal immune function; vitamin C, D<sub>3</sub>, manganese, and zinc maintain muscle and connective tissue function. Vitamins B<sub>2</sub> and C, zinc, and manganese are of particular importance to the antioxidant protective system. Magnesium helps to maintain the electrolyte balance and, together with vitamins  $B_6$  and  $B_1$ , is important for normal muscle and nerve function. Magnesium, vitamins B2, B3, B<sub>6</sub>, B<sub>12</sub>, pantothenic acid, folic acid, and vitamin C reduce fatigue and exhaustion.

#### **Acidosis**

The acid-base balance is usually precisely regulated, as even slight deviations could lead to severe organ damage. Especially in CAM, generalised acidosis of the body is seen as the cause of many health problems – ranging from chronic fatigue and muscle pain to cardiac arrhythmias and cancer, allergies, arthritis and rheumatic disease. Possible causes of acidosis include having too much acid-producing food in the diet (sugar, sweets and cakes, white bread, pasta, meat, sausages, cheese, eggs etc.) or the excessive production of free radicals in the body.

#### **How Regulat helps**

- Because of its phytochemicals, Regulat undergoes basic (alkaline) metabolism.
- It has antioxidant effects and reduces reactive oxygen and nitrogen species to healthy levels with the result that there is no acid production in the tissues.
- Regulat significantly increases intracellular reduced glutathione, the key natural protective system against oxidative stress. Free radicals in the cells and mitochondria are neutralised.
- Deacidification of the body is not based on transient buffering of acids by supplying basic components. Instead, fundamental enzymatic feedback loops ensure the natural regulation of the acid-base balance.

# Dermatology/phlebology

### **Allergies**

Allergies arise from contact with a normally harmless substance that induces an excessive immune response of a specific type. Medical conditions that may occur as a result of an allergic reaction in the skin include contact dermatitis (contact eczema) and urticaria (hives, nettle rash). Chronic eczema may also develop.

#### How Regulat helps

- Regulat affects only cells concerned with nonspecific immunity and not those responsible for the specific immune responses that trigger allergies. The immune system is thus adjusted to a healthy equilibrium.
- There is no stimulation of the secretion of interleukin-4 (IL-4), there is no provocation of atopy and allergic reactions.
- Increased secretion of interleukin-10 (IL-10) indicates protection against allergy. IL-10 is important for the development of immune tolerance and helps prevent excessive immune reactions.
- Probiotic lactobacilli cell wall components counteract allergy.
- The potent anti-inflammatory effects of Regulat improve inflammatory skin reactions.

### **Atopic dermatitis**

Atopic dermatitis (atopic eczema) is a chronic or chronically recurring inflammation of the skin with sometimes unbearable itching. While the cause remains unclear, allergies may be involved. Patients with atopic dermatitis often also suffer from other allergic conditions such as asthma, hay fever and food allergies – this state is referred to as atopy. The complex clinical picture of the condition suggest the interaction of genetic factors, immunological changes and environmental influences.

#### **How Regulat helps**

- Regulats prevent excessive inflammatory reactions.
- The *in vitro* model shows that they reduce pro-inflammatory cytokines such as interleukin-6 (IL-6) and interferon gamma-induced protein (IP-10), which are involved in atopic dermatitis.
- Resultant anti-inflammatory effects are comparable to those of the corticosteroid dexamethasone.
- *In vitro/ex vivo* experiments confirm the increased secretion of IL-10, which is important for the development of immune tolerance.
- Also of interest are the probiotic effects of Regulats, which can reduce the risk of atopic dermatitis.

A combined use of Regulat is recommended for severe atopic dermatitis. For example, in addition to taking the Regulat orally, RegulatPro® Bio is diluted 1:1 with water and sprayed onto the affected skin. It is also possible to mix a few sprays of Regulat with skincare products for very dry skin, in the hand, before application. Cotton-wool pads soaked with Regulat and

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#### Atopic dermatitis before (left) and after (right) three weeks' treatment with oral and topical Regulat







wedged between the toes (with loose-fitting socks on top) may help the patient to sleep undisturbed at night.

#### Study data of interest

The anti-inflammatory properties of Regulat were demonstrated using the *in vitro* model of atopic dermatitis.<sup>11</sup> Skin epithelial cells were cultivated together with activated T lymphocytes. Activation causes the T lymphocytes to secrete messengers that provoke the skin cells into manifesting symptoms and signs of atopic dermatitis. Inflammatory processes in the skin cells can be quantified by measuring the release of pro-inflammatory cytokines.

The corticosteroid dexamethasone (10 µM topically and in the medium) served as the positive control, which reduced secretion of IP-10 (which recruits monocytes, T cells, NK cells and dendritic cells for inflamed tissue) to about 50%. Regulat® Cosmetic Body Foam (1:3 dilution) reduced the IP-10 secretion to levels of about 8% that were even comparable to those of the negative control (non-activated T lymphocytes). Regulat® Bio-Spray SKIN REPAIR (1:3 dilution) was as effective as dexamethasone (approximately 50%). Earlier testing in a similar in vitro model showed that Regulat® Cosmetic Body Foam considerably reduced the secretion of IL-6, comparable to the reduction seen with the positive control dexamethasone. 12

#### An in vitro model of atopic dermatitis shows that Regulat® Cosmetic Body Foam has an antiinflammatory effect comparable to that of the corticosteroid dexamethasone, established by the IL-6 values (control: cultivated with activated lymphocytes but not treated)<sup>11</sup> as well as the IP-10 values Interleukin-6 after 24 h IP-10 48 h after triggering the inflammatory reaction Regulat® Control Dexa-Activated Dexa-Hyaluron- Regulat Cosmetic methasone T cells methaic acid 1:3 **Body Foam**

#### **Psoriasis**

Psoriasis is a chronic inflammatory skin disease characterised by severe flaking. Immunological mechanisms probably play a role. Flares occur particularly in winter and following stress. It has recently been established that the underlying chronic inflammation may also lead to metabolic syndrome and cardiovascular problems. Some patients also have joint involvement (psoriatic arthritis).

#### **How Regulat helps**

- The potent anti-inflammatory effects on the skin promote healing of inflamed psoriatic lesions.
- They also have an effect on joint problems.
- Stress-induced reactions are reduced.
- Given the involvement of immunological mechanisms, the immunoregulatory effects of Regulat may be beneficial.
- The enzyme-regulating and antioxidant properties are also interesting in relation to possible metabolic problems and vascular changes.

Patients and therapists report good results with the topical use of Regulats on circumscribed psoriatic lesions. RegulatPro® Bio is diluted 1:1 with water and sprayed onto the affected areas twice or three times a day. The bioconcentrate can also be taken orally in the usual way (10 ml, morning and evening).

### **Disorders of wound healing**

While most wounds heal without much problem, the main disruptive factors in wound healing are ischaemia (impaired blood perfusion) and/or infection. Wounds that are difficult to heal include pressure sores (decubitus ulcers) and leg ulcers with chronic venous insufficiency (ulcus cruris).

#### **How Regulat helps**

- The enzyme-regulating and immunoregulatory properties of Regulat support the repair metabolism and thus the healing process.
- Regulat boosts nonspecific immunity, which combats invading pathogens.
- Regulat also acts directly to render bacteria and fungi harmless, as shown by the microbial challenge test.
- The antioxidant properties protect against damage from the excessive production of reactive oxygen species.
- The improved energy supply of the cells (increase in intracellular ATP) promotes the necessary anabolic and catabolic processes in the wound area.
- Venous or arterial circulatory problems may also be improved by Regulat.

#### **Please note**

Small wounds such as cuts, burns or abrasions heal more rapidly and are less painful when sprayed with RegulatPro® Bio (mixed 1:1 with boiled water).

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#### **Infections**

Skin infections may be caused by various pathogens: bacteria (e.g. boils and acne), viruses (e.g. warts and cold sores) or fungi (e.g. athlete's foot and candidiasis).

#### **How Regulat helps**

- Regulat acts directly to render bacteria and fungi harmless, as proven by the microbial challenge test.
- Increased nonspecific immunity means better protection against invading pathogens.
- Enzyme-regulating, anti-inflammatory and antioxidant properties prevent excessive reactions and promote the healing of skin lesions.
- The improved energy supply to the cells (more intracellular ATP) with Regulat supports the functional capacity of those cells particularly involved in combating infection.

Spraying the infected skin with RegulatPro® Bio mixed 1:1 with boiled water several times a day relieves symptoms and helps the infected areas to heal. Regulat can also be used to soak dressings.

# Skin conditions of unknown aetiology

A very wide range of skin and mucous membrane conditions respond well to Regulats. This is hardly surprising as inflammation and/or immunological dysfunction is very often involved. The anti-inflammatory and immunoregulatory efficacy of Regulat have been demonstrated in several studies. Improved energy supply to cells and reduced oxidative stress also contribute to restoring the natural homeostasis of irritated or diseased skin.

#### **Anti-ageing with Regulat**

Regulat may also help to combat signs of ageing in the skin. This has been demonstrated by studies in which the effects of these bioconcentrates have been tested in various in vitro models of ageing. 13 Treatment of artificially aged keratinocytes with Regulat led to strong dose-dependent activation of proteasomes. These protein complexes, which break down damaged proteins and signalling proteins, are important in maintaining cell functionality. With diminishing proteasome activity, cells are overloaded with non-functional proteins. This is an important aspect of cell ageing and may be the cause of the reduced cell division in ageing skin cells. The ATP content of the keratinocytes also increased considerably under the influence of Regulat. ATP is the most important energy supplier for cells and pivotal to their functional capacity.

# Gastroenterology

### Gastritis/reflux disease

Gastritis is inflammation of the mucosal lining of the stomach. It may be triggered by infections, injuries, and disorders of the immune system but also by stress (stress gastritis) and medicines such as acetyl salicylic acid (ASA, aspirin) and non-steroidal anti-inflammatory drugs (NSAIDs). The most common cause of gastritis is infection with the bacterium *Helicobacter pylori*. As a rule, gastric mucosal inflammation causes very little in the way of symptoms or even no symptoms at all. Some of the people affected complain of epigastric pain, belching, nausea and digestive upsets.

Acid reflux and heartburn, on the other hand, are symptoms of gastrooesophageal reflux disease (GERD). Reflux of gastric acid and digestive enzymes into the oesophagus occurs when the lower oesophageal sphincter – a ring of muscle where the oesophagus enters the stomach – does not function properly. Aggressive stomach contents may cause severe inflammation of the oesophageal mucosa. Fatty foods and chocolate increase the risk of reflux. Alcohol and coffee are also detrimental as they stimulate gastric acid production.



#### **How Regulat helps**

- It is often impossible to distinguish clinically between gastritis and reflux disease. Taking Regulats with their regulatory properties is worthwhile in both these medical conditions.
- Regulat balances the enzymes and improve the energy supply in the cells.
- The anti-inflammatory effects of Regulat helps the inflamed mucosa in the stomach or oesophagus.
- Oxidative stress and acidosis decrease.
- As Regulat boosts immunity and have antibacterial effects, it makes sense to take them in case of possible infection.
- Many patients, some of whom have suffered from belching and heartburn for years, report more ordered digestion and rapid improvement in their symptoms.

**Overview of the indications** 

# **Chronic inflammatory bowel** disease (ulcerative colitis,

Crohn's disease)

Crohn's disease and ulcerative colitis are characterised by tenacious inflammation of the intestinal wall. Patients suffer repeatedly from abdominal pain and severe, sometimes bloody, diarrhoea with fever. Crohn's disease usually involves the distal segment of the small intestine and the large intestine. In ulcerative colitis, inflammation affects mainly the rectum and the distal colon. The cause of these chronic inflammatory bowel diseases is not clear. Malfunction of the immune system in the intestinal tract, overreacting to environmental factors, diet or micro-organisms, has all been suggested. Genetic factors also appear to play a key role.

#### **How Regulat helps**

- Patients with chronic inflammatory bowel diseases require effective anti-inflammatory treatment. The biological Regulat with its potent anti-inflammatory properties has offer a number of important benefits.
- The immunomodulatory effects of Regulat are also beneficial.
- The enzyme building blocks and valuable protective and essential nutrients compensate for any deficiencies.
- Oxidative stress is reduced; the intracellular energy supply is increased.
- Regulat regulates digestion and metabolism.

#### Please note

Start treatment with a low dose of diluted Regulat.

#### Irritable bowel

Irritable bowel syndrome (IBS), also known as irritable colon, is the most common functional gastrointestinal disease. Even mild irritation may lead to abnormal contractions of the gastrointestinal tract muscle. Typical symptoms are diarrhoea and constipation, often occurring alternately; abdominal pain and cramps, which are usually better after defaecation; flatulence with bloating and abdominal distension. Difficulties swallowing, belching, and nausea may also occur. Women are three times more likely to suffer from IBS than men. Many patients have an abnormal gut flora.

#### **How Regulat helps**

- It improves all significant irritable bowel symptoms, whether diarrhoea, constipation, flatulence, bloating, abdominal pain or cramps.
- Dextrorotatory lactic acid in Regulat acidifies the intestines and promotes a healthy composition of the gut flora. This in turn improves the immune defences and reduces flatulence, makes food more tolerable, and helps to maintain the integrity of the intestinal mucosa.
- · Secondary plant metabolites increase immunity and reduce the stress caused by free radicals. This in turn reduces inflammatory processes involving the nerve plexuses and cell damage in the mucous membranes.
- Extracted enzymes improve food utilisation. Substances that may cause flatulence are broken down.
- Lactobacilli cell wall components activate the immune system. Defences against pathogenic bacteria are boosted, while excessive allergic and inflammatory processes are suppressed.

### Study data of interest

Taking Regulat is worthwhile when IBS is present, as demonstrated by a prospective single-centre non-interventional study.<sup>14</sup> All participants had irritable bowel syndrome according to the ROM-II criteria of the Deutschen Gesellschaft for Verdauungs- und Stoffwechselkrankheiten [German Society for Digestive and Metabolic Disorders] (DGVS): 40% diarrhoeal type, 23.5% constipation type, and 36.5% with alternating constipation and diarrhoea. They took a large dessert spoon of RechtsRegulat® (= 10 ml) every morning for eight weeks. No further measures were introduced - there were no changes in either diet or exercise. The analysis included 52 participants.

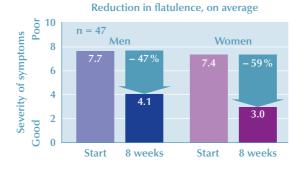
On Regulat therapy, symptoms improved in 82.5% of the patients with IBS, 55.5% rating the improvement as considerable and 27% as slight. Patients suffering predominantly from diarrhoea benefited the most (improvement in 92%).

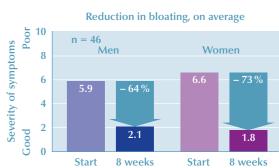
Six symptoms of IBS were included in a questionnaire and all these symptoms regressed. Abdominal pain, cramps and constipation showed a statistically significant difference while improvements in diarrhoea, flatulence and bloating were highly significant. It was also encouraging to find that the cascade-fermented bioconcentrate was well tolerated; 90.5% of the participants rated its tolerability as good or very good.

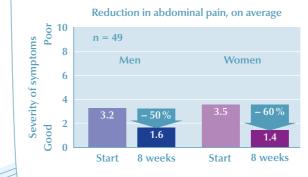
#### Results of the IBS study<sup>14</sup> with RechtsRegulat<sup>®</sup> at a glance

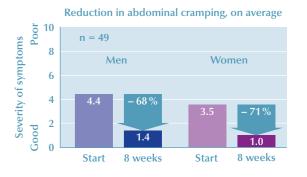












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### **Food allergies**

Many foodstuffs may trigger allergic reactions, e.g. milk, eggs, fish, shellfish, peanuts and wheat. Young children often present with eczema (atopic dermatitis) or urticaria (hives, nettle rash) as the first sign of allergy but sometimes with nausea, vomiting and diarrhoea. Adults often experience itching in the mouth, urticaria, eczema, occasionally rhinorrhoea, and asthma. In individual cases there may be massive swelling and shock. Although people with allergies should avoid the foods responsible, this is not always possible. Intolerance of certain foods also gives rise to pseudoallergies where allergy-like symptoms occur without the immune system being involved.

#### **How Regulat helps**

- Probiotic cell wall components from the added lactobacilli boost immunity and have immunomodulatory effects.
- Early probiotic therapy can reduce the occurrence of food allergies by inducing intestinal immunity.
- Regulat affects only cells concerned with nonspecific immunity and not those responsible for the specific immune responses that trigger allergies. The immune system is adjusted to a healthy equilibrium.
- As it does not stimulate the secretion of interleukin-4 (IL-4), there is no provocation of atopy and allergic reactions.
- Increased secretion of interleukin-10 (IL-10) indicates protection against allergy. IL-10 is important for the development of immune tolerance and helps prevent excessive immune reactions.

- All the ingredients in Regulat have lost any allergenic potential they may have had.
   Allergenic proteins have been cleaved to give non-allergenic oligopeptides and amino acids. This improves not only allergies but also food intolerances.
- "Alternating therapy" (see page 84) is recommended.

### **Diarrhoea/constipation**

Diarrhoea means that a significant watery stool is excreted several times a day. It is often associated with flatulence, cramps, urgency of defaecation, nausea and vomiting. There are many different causes of diarrhoea, including medication, infections, particular foodstuffs, stress, and tumours, as well as chronic diseases such as IBS, Crohn's disease and ulcerative colitis. With constipation, those affected pass stools only rarely; the stools are hard and often difficult, if not painful, to excrete. Lack of exercise, dehydration and a diet low in fibre may all lead to constipation; other causes include innumerable medicines and diseases such as hypothyroidism, Parkinson's disease and IBS.

### **How Regulat helps**

- Thanks to its regulatory effects, Regulat can improve matters considerably in cases of both diarrhoea and constipation, as demonstrated by impressive outcomes in the irritable bowel study.<sup>14</sup>
- The probiotic components of Regulat improve the bacterial equilibrium in the intestines and maintain a healthy gut flora.
- · Regulat combats infections and inflammation.
- The supply of extracted enzymes allows better food utilisation.
- Regulat increases mitochondrial function, and hence energy production, which supports digestion.

# Musculoskeletal system

# Rheumatoid arthritis/osteoarthritis

Rheumatoid arthritis (RA), sometimes also called chronic polyarthritis, is an inflammatory joint disease that usually affects the small joints of the hands and feet initially and spreads gradually to other joints if untreated. The joints are inflamed, swollen, painful and often stiff. With time, they become deformed and are finally destroyed completely. Some patients with RA also complain of weakness and fatigue. It has been suggested that RA is an autoimmune disease, in which the immune system attacks the body's own tissues.

In contrast, osteoarthritis (OA) is primarily a degenerative joint disease, also referred to as degenerative arthritis. But inflammatory proces-

ses have a key role in promoting the progressive destruction of the joint cartilage. OA usually affects the finger joints, metacarpophalangeal joint of the thumb, big toe, knee and hip joints but may also involve the spine. It has an insidious onset, with gradually increasing pain that is worse on joint loading. The affected joint loses mobility and becomes thickened due to remodelling processes and effusion and may gradually become completely stiff.

#### **How Regulat helps**

- The immunoregulatory effects help to restore the balance of the immune system and eliminate harmful immune complexes.
- The potent anti-inflammatory effects of Regulat act to suppress inflammation in the joints.

### An end to arthritic pain

A 52-year-old patient suffered from osteoarthritic pain and inflammatory swelling in both knees. She was able to walk only with the help of two sticks and had pain at rest and at night. An orthopaedic surgeon told her she would just have to live with it.

Initially, the patient wrapped her knees three times a day with dressings soaked in Regulat diluted 1:3 with water, using hot or cold water depending on preference. She put a linen cloth soaked with the Regulat solution over the painful areas for 20 minutes at a time and covered them with a small and large towel.

After three days, the pain had diminished. The joints were once again mobile and she no longer needed the walking aids all the time. One week later she returned to work.

Instead of the time-consuming dressings, her topical therapy then consisted of spraying undiluted Regulat onto the joints two or three times a day using a spray bottle. She also took one dessertspoonful of Regulat by mouth, morning and evening.

The patient was able to dispense completely with the walking sticks after three weeks' treatment, by which time the pain had abated and the knee joint swelling had almost completely resolved.<sup>18</sup>

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- Regulat contributes to resolving rheumatic symptoms by deacidification, protein anabolism and maintaining a healthy bacterial gut flora.
- The antioxidants present combat oxidative stress.
- Improved energy supply in the cells has beneficial effects on general well-being.
- Painful and/or inflamed joints can be treated not only with oral Regulat. Dressings with the bioconcentrate (diluted 1:1 or 1:3 with water) are also helpful.

#### Gout

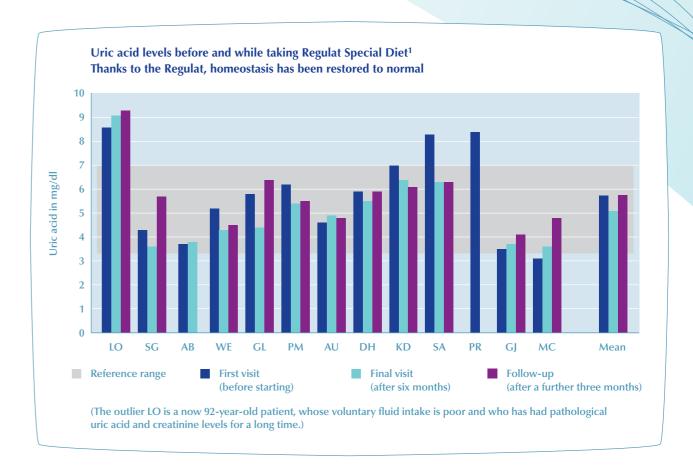
Gout is caused by the deposition of uric acid crystals in the joints. This results in the recurrent sudden onset of very painful inflammation of the joints, which become hot, red and swollen. Untreated attacks of gout become more frequent, last longer and affect progressively more joints which may then be permanently damaged. Hard uric acid nodules, known as "gouty nodules", form in the skin over the joints, the ears, the elbows, the Achilles tendon, and the kidneys. Many patients with gout also have kidney stones, which may cause considerable renal damage. Gout is due to elevated levels of uric acid in the blood (hyperuricaemia) because of reduced excretion, increased production or an increased intake of purines, the precursors of uric acid. Liver, kidneys, anchovies, molluscs and fungi are rich sources of purines. Alcohol makes the problem worse, as it increases the production of uric acid and impairs excretion of it via the kidneys.

#### **How Regulat helps**

- The enzyme regulatory effects of Regulat improve the metabolic situation and lower uric acid levels in the blood.
- Improved excretory kidney function following the use of Regulats also has beneficial effects.
- Regulat ensures a natural regulation of the acid-base balance.
- The anti-inflammatory effects counteract inflammation and prevent progressive damage to the joints.
- It is also relevant that the supply of secondary plant metabolites reduces oxidative stress.

#### Study data of interest

Two prospective studies from a CAM practice looking at patients with metabolic conditions, although not specifically gout, demonstrated the effects of Regulats on uric acid levels. Thirteen patients with type-2 diabetes and/or metabolic syndrome took part in the first study. 9 After three months taking Regulat Special Diet (10 ml, morning and evening), the mean uric acid level had fallen from 5.7 mg/dl to 4.8 mg/dl; after six months, it was 5.1 mg/dl. At follow-up three months later, the levels in the nine patients who had not continued to take Regulat had gone up again - the mean uric acid level was now 5.8 mg/dl. This study also found improved creatinine and electrolyte values – a sign of improved excretory kidney function.



### **Fibromyalgia**

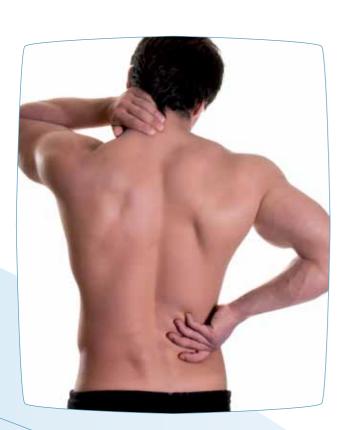
Fibromyalgia is a common medical condition, characterised by pain, tenderness and stiffness in muscles, tendons and ligaments. Muscles at the back and front of the neck, in the shoulder girdle, chest, back or thigh may be affected. Symptoms of fibromyalgia may involve the whole body and are particularly bothersome in (young) women. Long-term physical or mental overexertion, sleep disorders, injuries, cold or humidity have all been implicated as triggers. Hypothyroidism may also cause symptoms of fibromyalgia. With local fibromyalgia, pain and muscle stiffness is localised to certain areas. The trigger is often overuse of the affected area at work or during sporting activities.

### **How Regulat helps**

- Regulat modulates and balances all cell processes with the support of natural feedback loops and enzyme systems.
- The improved energy supply in the cells has beneficial effects on muscles and their functional capacity; tenderness abates.
- Oxidative stress and acidosis are reduced.
- Most patients find that they feel more energetic and well-balanced when taking Regulat. This also has beneficial effects on possible stress-induced symptoms.
- Many patients with painful conditions related to the musculoskeletal system report improvement of their symptoms with the regular consumption or external application of Regulat.

#### **Chronic muscle tension**

Chronic muscle tension is common today. The neck and back are particularly affected; the condition is usually due to poor posture or abnormal biomechanical stress. Causes include stress in everyday life, unilateral biomechanical stress at work, sitting in front of the computer for long periods, poor posture, and the wrong technique lifting or carrying when doing heavy physical work. The overloaded muscles cramp, are no longer adequately supplied with oxygen, and eventually become hard. Associated pain causes other muscle groups to tense – a vicious



circle of events. Injuries, as well as congenital or acquired misalignment of the musculoskeletal system, may also cause muscle tension.

#### **How Regulat helps**

- Natural regulatory processes are reinforced and homeostasis restored.
- Improved energy supply to the cells helps the muscles to regain an appropriate muscle tone.
- The improved supply of antioxidants protects against the detrimental effects of reactive oxygen species.
- Regulat ensures a natural regulation of the acid-base balance, counteracting acidosis in the muscles.
- Most patients find that they feel more energetic and well-balanced when taking Regulat. This has beneficial effects on any stress-induced muscle tension.
- · Many patients with painful conditions related to the musculoskeletal system report improvement of their symptoms with the regular consumption or external application of Regulat. It is recommended that the affected area is sprayed morning and evening with Regulat, diluted 1:1 with water, and allowed to dry in the air.

# ENT

#### **Sinusitis**

Inflammation of the nasal sinuses is almost always found in association with a cold of viral origin. When the nasal mucosa swells during a cold, the sinus openings are blocked, leading to inflammation, blocked up secretions, and the risk of bacterial infection. Acute sinusitis presents with pain, tenderness, and swelling over the affected sinuses. The nose is blocked, secretions are viscous or purulent. Symptoms of chronic sinusitis are usually less conspicuous: blocked nose, obstructed nasal breathing, mucus at the back of the throat, possible nasal secretions, limited pain.

Treatment should increase the flow of secretions and bring the inflammation under control. Experts consider that antibiotics are used far too often in acute sinusitis. Surgery may be required for refractory sinusitis in order to clean out the sinuses and to improve aeration and drainage so that the inflammation can heal.

### **How Regulat helps**

- Regulat brings neutrophil granulocytes into a "pre-alarm" state. These cells engulf and destroy viruses, bacteria, and fungi that have invaded the body.
- The lytic activity of natural killer cells, which kills viral-infected cells and bacteria, is strengthened.
- · Regulat also has direct antibacterial and antimycotic effects, as demonstrated by the microbial challenge test.

- Increased release of tumour necrosis factor alpha (TNFα) also contributes to boosting immunity.
- On the other hand, stimulation of interleukin-10 release prevents excessive TNFα
- Thanks to their anti-inflammatory effects, Regulat reduces swelling and aid the healing of inflamed mucosa.
- With sinusitis or rhinitis, good results are achieved not only by taking Regulat orally but also by their application as a nasal spray (mixed 1.3 with water).

#### Chronic sinusitis finally cured

A 32-year-old patient had chronic frontal sinusitis with some pus formation in the maxillary sinus. Heat therapy, decongestants, and even surgery had not been successful over the long-term.

Finally, he tried Regulat. The patient took two dessertspoonfuls every morning and evening. In addition, he was supposed to apply a dressing soaked with Regulat diluted 1:1 with water on the affected areas of his face, for 20 minutes morning and evening and, if possible, to sit under an infrared lamp (pressure of time meant that he applied the dressing only in the evenings). In addition, he sprayed Regulat, diluted 1:3 with water, into the nostrils every hour, using a nasal spray bottle. After only two days, the pain had abated. After five days, there was a sudden discharge of pus and mucus from the nose and mouth. The chronic sinusitis then healed.<sup>18</sup>

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# **Allergic rhinitis**

Allergic rhinitis is due to a reaction of the specific immune system to a trigger, the allergen. The most common allergens are house dust, mould spores, grass and tree pollens, animal hair, and feathers. Contact with the allergen sets things in motion - sneezing, runny or blocked nose, itchy and watering eyes. Depending on when the allergens are present, allergies may be seasonal (hay fever) or occur at any time of the year (perennial rhinitis). Pharmacotherapy aims to combat the inflammatory reaction and relieve the allergic symptoms. Sustained tolerance of some allergens can be achieved with specific immunotherapy (desensitisation/hyposensitisation). Rhinitis that is not adequately treated may develop into allergic asthma.

#### **How Regulat helps**

- Regulats affect only cells concerned with nonspecific immunity and not those responsible for the specific immune responses that trigger allergies. The immune system is adjusted to a healthy equilibrium.
- As Regulat does not stimulate the secretion of interleukin-4 (IL-4), there is no provocation of atopy and allergic reactions.
- Increased secretion of interleukin-10 (IL-10) indicates protection against allergy. IL-10 is important for the development of immune tolerance and helps prevent excessive immune reactions.
- Probiotic lactobacilli cell wall components counteract allergy.
- The anti-inflammatory effects of Regulat helps improve mucosal inflammation.

#### Help for hay fever

Every spring for many years, a 35-year-old patient had been bothered by the typical symptoms of hay fever.

Finally, she tried Regulat. She took Rechts-Regulat® by mouth twice a day. In addition, she put two cotton wool balls soaked with Regulat, mixed 1:2 with water, on her closed eyelids for 20 minutes. Using a spray bottle, she sprayed Regulat, mixed 1:3 with water, into her nose several times a day.

The results were convincing: the attacks of sneezing and watering eyes improved considerably. The swelling and redness in her face had disappeared after only three days.<sup>18</sup>

# Oncology

#### **Mucositis**

Inflammation of the mucous membranes occurs frequently in patients with cancer who have to undergo treatment with chemotherapy (including biological therapies such as interferon and targeted agents such as tyrosine kinase inhibitors) and/or radiotherapy. Oral mucositis is characterised by erythema and ulceration, and possibly also bleeding; it can cause severe pain and make eating difficult. There is an increased risk of local and systemic infection. It is not always possible to suppress the symptoms with standard therapeutic measures.





Mucositis due to radiotherapy in a patient with oropharyngeal carcinoma; mucosal changes affect only the irradiated surface (left). In contrast, mucositis due to chemotherapy affects the mucosa of the entire oral cavity (right).

### **How Regulat helps**

- The enzyme-regulating, antioxidant, immunomodulatory and anti-inflammatory effects can be used for the prophylaxis and treatment of mucosal damage due to cancer treatment.
- Oral mucositis can be prevented or attenuated in cancer patients undergoing chemotherapy or combined chemo- and radiotherapy.
- Oral mucositis can be healed within three to four weeks.

#### Study data of interest

The usual measures to prevent or treat oral mucositis in patients with cancer are based on oral hygiene, dealing with infected sites in the teeth and gums, antimicrobial products, anti-inflammatory drugs and analgesics. In an Italian pilot study at the Milan University Hospitals, patients on chemotherapy or combined chemo- and radiotherapy who agreed to an unconventional approach to the prophylaxis and treatment of oral mucositis, were instead treated with RechtsRegulat®.15 Nine patients, six with ENT cancers, participated in the study. These patients had chemotherapy induction, then combined chemo- and radiotherapy. Before and during the cancer treatment, all of them used RechtsRegulat® six to eight times a day as a mouth spray (diluted 1:1) and also took a dose of one dessert spoon twice daily.

# Classification of oral mucositis (WHO 1979)

Grade 0: None

Grade 1: Pain in the mouth, erythema

Grade 2: Oral erythema, ulceration

Patient can eat solids

Grade 3: Oral ulceration

Patient can only take liquids

Grad 4: Oral intake not possible

#### **Overview of the indications**

The results were encouraging. Six patients experienced only local toxicity (Grade 1). Although two patients had more marked mucosal changes, they were still able to eat normally (Grade 2). One patient had no signs of oral mucositis at all. During this patient's first cycles of chemotherapy (with the so-called FOLFOX regimen) he had developed severe local toxicity; during the next chemotherapy cycles (with the FOLFIRI regimen), under Regulat protection, he remained symptom-free.

A clinical study by Dr Peter Holzhauer, Department of Oncology and Complementary Medicine, Bad Trissl Hospital, also had a positive outcome. 16 Eleven (male and female) patients who had suffered from chemotherapy-induced mucositis were instructed to rinse their mouths out several times a day with RechtsRegulat® for three to four weeks.

The severity of the mucositis was ranked (score up to 8 points: no mucositis, 9-16 points: moderate mucositis, 17-24 points: severe mucositis). The mean score at baseline was 12.73. After treatment with RechtsRegulat®, this fell to 8.27 - Dr Holzhauer said he was extremely happy with its "amazing effectiveness".

#### Recording and evaluation of oral conditions

Category	1	2	3
Voice	Normal	Deep or rough	Difficulty/pain on speaking
Swallowing	Normal	Somewhat painful	Unable to swallow
Lips	Smooth, pink and moist	Dry and cracked	Ulcerated or bleeding
Tongue	Pink, moist and with papillae	Coated or loss of papillae, appears shiny with or without redness	Blisters present, or cracked
Saliva	Watery	Thick or viscous	None
Mucous membranes	Pink and moist	Reddened or coated (whitish in several places) without any ulceration	Ulceration with or without bleeding
Gums	Pink and firm	Oedematous with or without reddening	Spontaneous bleeding or bleeding under pressure, e.g. on biting
Teeth/ dental prostheses	Clean, no deposits	Dental calculus or local deposits (if present, between the teeth)	Dental calculus or generalised deposits in the zone between teeth and gums
Evaluation (sum of	all points)		
Up to 8 points	No mucositis		
9–16 points	Moderate mucositis		
17–24 points	Severe mucositis		

modified from Eilers et al. "The Oral Assessment Guide (OAG)". 1988, 2003



# **Dietary deficiency**

Many patients with cancer lose their appetites and/or no longer tolerate certain foods. For example, they have to forego eating raw vegetables and have problems eating fruit. This may lead to dietary deficiencies and an inadequate supply of vitamins, trace elements and other essential nutrients.

#### **How Regulat helps**

- The supply of essential amino acids, di-, triand oligopeptides, polyphenols, vitamins, minerals, etc. is improved.
- Appetite increases.
- Energy deficiencies in the cells are overcome (increased intracellular ATP).
- The dextrorotatory lactic acid in Regulat acidifies the intestines and promotes a healthy composition of the gut flora. This in turn provides better immunity and less flatulence, makes food more tolerable and helps maintain the integrity of the intestinal mucosa.
- Immunity increases.

### **Post chemotherapy** (detoxification)

During chemotherapy, cancer cells are killed by means of direct toxic actions. Unfortunately, all chemotherapeutic agents also act on normal cells and this leads to a wide variety of unwanted side effects. For example, many patients suffer from nausea, vomiting, loss of appetite and fatigue; they may also be anaemic and have a higher risk of infection or mucosal damage.

### **How Regulat helps**

- Regulat supports detoxification of the body. The supply of phenolic acids induces detoxifying enzymes and promotes the excretion of chemotherapeutic drugs.
- Reduced glutathione, which the liver requires for phase II detoxification, increases within the cells.
- Excretory liver and kidney function is increased.
- Oxidative stress abates; Regulat ensures a natural regulation of the acid-base balance.
- The cells are supplied with considerably more energy.
- The probiotic components contribute to restoring the normal gut flora.
- · Regulat promotes healing of the affected mucosa.

### Getting the side effects of chemotherapy under control

The use of Regulat is worthwhile in cancer patients for several reasons. The antiinflammatory effects can relieve some of the concomitant symptoms of cancer. The use of these cascade-fermented bioconcentrates during chemo- and/or radiotherapy may help to deal with many of the stressful side effects of treatment, as illustrated by the following case report.

A 61-year-old patient had a leiomyosarcoma, a malignant myoma of smooth muscle fibres, for eleven years. Tumours had been removed from various organs in six operations. Two tumours on the pancreas and in the liver, however, were inoperable.

During a clinical trial of a newly-developed chemotherapeutic drug, he experienced considerable side effects with treatment: facial oedema, oral mucositis, hand-foot syndrome, general fatigue, loss of drive, increased pain in the scars, and periodic spikes of fever.

A doctor (who was also a friend) told the patient about Regulat. In order to overcome the side effects of the chemotherapy, he started to take Regulats concomitantly, at the standard dose of two dessert spoonfuls daily for the first two weeks.

A slight improvement in symptoms was soon noted, so the patient tripled the dose of his own accord (two dessert spoonfuls, morning, midday and evening). In addition, he sprayed his hands and feet with Regulat, mixed 1:1 with water.

After three months he was free of side effects from the chemotherapy. The mucositis had disappeared within four weeks. In addition, recent routine computed tomography (CT) and magnetic resonance imaging (MRI) examinations showed tumour regression.<sup>18</sup>

# Mental health

### **Burnout syndrome**

As a rule, burnout syndrome develops over a sustained period of time. Those affected feel worn out and emotionally exhausted. Prolonged stress at work or in the family usually contributes to burnout, which often affects people who are deeply committed to a task who push their own needs to the background but get little recognition. They become gradually more resigned and withdrawn. Over time, they develop physical symptoms such as headache, fatigue, difficulties sleeping, gastrointestinal upsets and muscle cramps and become more susceptible to infections. It is extremely important for these people to find a healthy balance between workrelated/family stress and relaxation or leisure activities.

# **Chronic fatigue**

Fatigue (exhaustion) is an everyday phenomenon, it can basically occur with any form of stress. It is estimated that 10-25% of patients visiting their general practitioner complain of feeling exhausted. However, many diseases cause chronic fatigue - anaemia, cancer, anxiety states, depression, diabetes mellitus, Lyme disease (borreliosis), multiple sclerosis, Parkinson's disease, hyper- or hypothyroidism. Vitamin  $B_{12}$  deficiency have to be excluded.

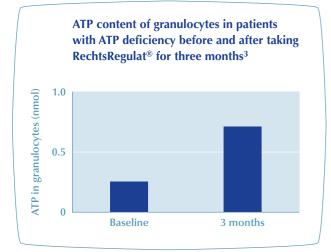
Chronic fatigue syndrome (CFS) is a medical condition that may even cause disability. It is characterised by a debilitating state of mental and physical exhaustion and exhaustibility, combined with further symptoms such as headache, joint and muscle pain, impaired concentration and memory, and non-refreshing sleep. The condition deteriorates markedly for some time after physical exertion. At the onset of illness, the patient often has a history of infection. Possible trigger mechanisms that are under discussion include immune dysfunction (weakened immunity or chronic activation of the immune system) or disruption of neuroimmunological regulation, leading to an imbalance in interaction between the immune, nervous and hormonal systems.



#### **How Regulat helps**

Whether it be a case of burnout syndrome or chronic fatigue – Regulat is extremely helpful in problems characterised by marked lack of energy:

- Regulat supports biological regulatory processes and have immunomodulatory effects.
- Intracellular ATP increases and thus the energy supply to the cells.
- Users of Regulat report that they feel invigorated, have perceptibly more energy, perform better, and are physically fitter but at the same time feel more relaxed with an inner calm.
- The powers of concentration increase considerably, daily lows abate and fatigue decreases.
- Sleep becomes deeper, longer and more refreshing.
- Regulat is also known to have beneficial effects on muscle cramps, joint pain, and gastro-intestinal problems, which may also occur in burnout syndrome and chronic fatigue.



# More power of concentration in seminars

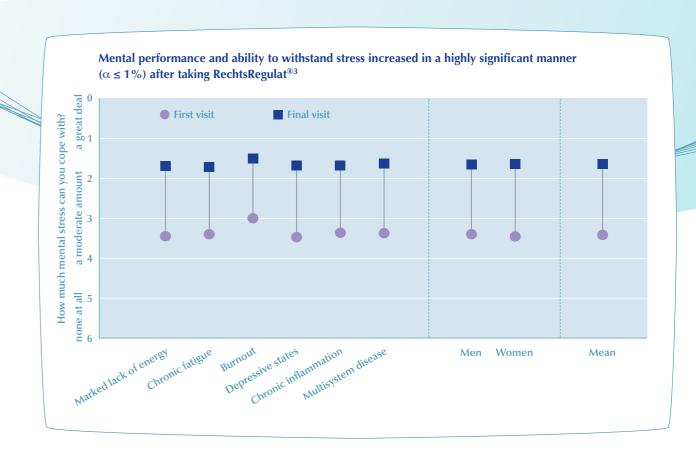
A management trainer sent the following report: In our work as leaders and trainers in company management, we conducted a trial of Regulat with ourselves as guinea-pigs. On the basis of our results, we decided to offer Regulat to participants in our seminars.

Since this trial, our seminars are more intensive. We are very impressed by the effects of Regulats. A series of participants have tested Regulat and, like us, have more stamina and greater powers of concentration. General well-being is considerably improved. We recommend RegulatPro® Bio!

### Study data of interest

Based on many years experience with Regulat, it is established that users report feeling much more energetic. Two prospective studies confirmed this finding – in a CAM practice, patients with metabolic problems felt more energetic and able to do things when taking Regulat Special Diet or RegulatPro® Metabolic, and were able to concentrate better.<sup>2,9</sup> One of the studies also determined intracellular ATP in four subjects: the mean increase in the "energy currency" of the cells when taking Regulat was 187%.

One prospective study looked at the effects of cascade-fermented bioconcentrates on the availability of ATP in the cells in people with a chronic lack of energy.<sup>3</sup> It included 31 patients in a CAM practice who had suffered for a long time from at least two of the following inclusion criteria: marked lack of energy (n = 29), chronic tiredness (n = 25) or chronic fatigue syndrome (n = 1), burnout syndrome (n = 4), depressive mood (n = 19), chronic inflammation (n = 22), and/or multisystem disease (n = 8).



Participants took 10 ml RechtsRegulat® mornings and evenings for three months. There was a mean increase of 55% in intracellular ATP in the granulocytes (lab reference range: 0.4–1 nmol). At the start of the study, 22 patients showed ATP deficiency. Taking Regulat for just three months led to a highly significant 183% increase of ATP in these patients (from a mean of 0.25 nmol to 0.72 nmol).

The patients reported a clear improvement in well-being. Amazing improvements in specific and nonspecific symptoms were also found in some cases. Physical fitness increased by 60% on average, powers of concentration by 59%, and the ability to cope with mental stress by 52%. Sleep disorders were reduced by 56%, patients slept deeper and longer and woke more refreshed. Daytime lows and fatigue lessened. Most participants felt more relaxed, calmer and more composed, but at the same time better able to do things.

### **Depression**

Low spirits and impaired sense of well-being are completely normal in everyday stressful situations or when fate strikes a blow. Depression, on the other hand, is a condition with many facets. Symptoms include depressed mood, particularly in the mornings (morning lows), lack of interest or pleasure in everyday activities and diversions, inhibited thoughts and actions, loss of drive and lack of energy, impaired concentration, fatigue and withdrawal, feelings of hopelessness and possibly suicidal thoughts. Sleep disorders, loss of appetite and digestive problems may also occur.

The origins of the condition are unclear. Multiple intrinsic and exogenous factors usually have to combine for the condition to develop. Disorders of neuronal metabolism and poor regulation of stress hormones are currently under discussion as possible explanations. Severe or

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chronic physical disease promotes depression. Low blood glucose, vitamin  $B_6$  or  $B_{12}$  deficiency, hypothyroidism and dementia can also be responsible for symptoms of depression.

#### **How Regulat helps**

- Regulat supports the biological regulatory processes and balance enzymes.
- In depression, the cells suffer from a lack of energy. Regulat considerably increases intracellular ATP levels.
- The improved supply of energy may have beneficial effects on the loss of drive and lack of energy in depressed patients.
- The possible influence on digestive problems, loss of appetite and sleep disorders make Regulats an interesting option in this medical condition.
- The immune system is restored to equilibrium; oxidative stress is reduced.

### Alzheimer's disease/dementia

In dementia there is gradual impairment of memory along with the progressive loss of other cognitive processes including decision-making capacity, concentration, and the ability to learn. Although dementia occurs mainly with advancing age, it is not a normal consequence of ageing.

There are various causes of dementia. The most common is Alzheimer's disease. The brain shows degenerative changes with neuronal loss and the formation of senile plaques and neurofibrillary tangles. How and why Alzheimer's disease develops is unclear; genetic factors do



seem to contribute. With vascular dementia (multi-infarct dementia), numerous small and possibly unnoticed strokes are responsible for the gradual destruction of brain tissue and the onset of dementia symptoms.

#### **How Regulat helps**

- Regulat prevents deficiency of essential nutrients and energy and support the body's natural regulatory systems.
- In dementia, the neuronal cells suffer from a lack of energy. On taking Regulat there is a demonstrable increase in intracellular ATP.
- Many people who take Regulat are able to concentrate and perform other cognitive tasks better. This may be relevant to incipient dementia.
- Oxidative stress, which seems to be a cause of Alzheimer's disease, is reduced.
- The antioxidant effects are also of interest in vascular dementia, as the protection from LDL oxidation demonstrated with Regulat counteracts arteriosclerotic changes.
- Regulat lowers the blood glucose and the blood pressure these effects may also delay the progression of multi-infarct dementia.

# Oral and dental medicine

#### **Periodontitis**

Periodontitis means inflammation of the gums which extends to the supporting structures of the teeth. It is the main cause of tooth loss in elderly people and is almost always due to inadequate oral hygiene. Bacterial deposits on the teeth (plaque) and dental calculus (tartar) which build up at the margins of the gums induce inflammation. With time, periodontal pockets develop and may extend to the roots of the teeth and underlying bone. Anaerobic bacteria, which are particularly harmful, colonise these pockets. Under these conditions, the plaque will extend deeper and deeper over time. The infection finally destroys the bone of the jaw holding the tooth in place. Without this support, the tooth becomes loose and falls out.

Interleukin-1 (IL-1) genetic testing may provide an indication of the individual's genetic risk of periodontitis. The pro-inflammatory cytokine IL-1 is released by monocytes when these immune cells come into contact with periodontitis

# The risk of periodontitis risk is increased with

- Poor oral hygiene
- Diabetes mellitus
- Side effects of medication
- Smoking
- Stress
- Hormonal changes
- Dietary deficiency
- Overweight
- Piercings (lips, frenulum of upper/lower lip, tongue)

bacteria. The more IL-1 secreted, the stronger the inflammatory reaction and the more rapid the breakdown of bone. If the gene test is positive – that is to say, a genetic code associated with increased IL-1 release is demonstrated on chromosome 2 – it indicates a higher risk of periodontitis with a severe course. About 30% of the population are IL-1 high responders.

#### **How Regulat helps**

- The bioconcentrate is ideal to use for periodontitis prophylaxis but also as an adjuvant to treatment.
- Strengthens gums and suppresses periodontal and gingival bleeding.
- Periodontal pockets become smaller, as shown by a pilot study.
- Restores and maintains the equilibrium of a healthy oral flora.
- The potent anti-inflammatory effects of Regulat on the skin and mucous membranes have been unequivocally confirmed in various studies.
- Regulat not only boosts nonspecific immunity and thus the defences against pathogenic micro-organisms but also has direct antibacterial and antimycotic effects when applied topically.
- The effects of improving circulation, stimulating cell metabolism and detoxification also need to be taken into account.

### Study data of interest

A pilot study in a Berlin dental practice showed that periodontal pockets reduced in depth on treatment with Regulat<sup>®</sup> Dent.<sup>17</sup> Forty-two patients with suspected periodontitis were first tested for the Interleukin-1 gene.

Some subjects had already been treated for periodontitis some years previously. Out of this preselected population of high risk patients, 21 (50%) were grade 3 or 4 IL-1 high responders. Following professional dental cleaning, they were treated with the Regulat for four weeks. No other therapeutic measures, such as curetting, scaling, ultrasound or other abrasive procedures, were used during this time. Invasive periodontitis therapy with an erbium: YAG laser was planned for some patients following the Regulat treatment.

Data from 18 patients were available for evaluation (two patients had been treated with antibiotics, one patient stopped using the Regulat).

#### Immediate relief for inflamed periodontal pocket

A 65-year-old patient was suffering from painful swelling over the two upper incisors. Her dentist lanced the gums, releasing a great deal of pus. The lesion healed after a while but there was a recurrence with pain and inflammation at the same place. She dreaded a repeat surgical intervention at the dentist's.

The patient was recommended to soak a cotton wool ball with Regulat and apply it to the affected gums. She experienced immediate relief and, contrary to instructions, left the cotton wool in place overnight. She then continued treatment twice a day, leaving the soaked piece of cotton wool on the gums for 20 minutes each time.

The periodontal pocket regressed, and the inflammation resolved. The original severe pain abated completely after the first Regulat applications and did not reappear. The patient has been symptom-free ever since.<sup>18</sup>

The depth of the periodontal pockets was measured at four separate sites before and after using Regulat. Results: the mean depth fell from 1.80 mm to 1.55 mm (-17%), an effect that could be attributed to the Regulat alone.

### **Oral thrush (candidiasis)**

Yeast infections of the oral mucosa, with Candida albicans in particular, form soft white patches that may be very painful. Candida is part of the normal flora of the skin, intestinal tract, and women's genital regions. The yeast usually causes no problems but infection may develop, especially in patients taking antibiotics. With the elimination of bacteria that are usually in competition with the fungi, Candida can multiply unhindered. Thrush also occurs more frequently and severely in people with diabetes mellitus, cancer or AIDS and in immunosuppressed patients. In immunodeficient people, candidiasis may affect the entire body via the blood system.

### How Regulat helps

- Regulat has potent anti-inflammatory effects on the oral mucosa, as demonstrated by two studies in cancer patients with oral mucositis.
- Pain in the mouth usually disappears rapidly.
- The bioconcentrate, which is rich in essential nutrients, boosts immunity and promotes a healthy oral cavity flora.
- The topical application of Regulat also provides direct antimycotic and antibacterial effects, as shown by a microbial challenge test.
- Stimulant effects on cell metabolism, as well as detoxifying and antioxidant properties, are beneficial.

# Oral and dental problems showing their teeth

Regulat is being used increasingly in dentistry. In this setting it has been show to:

- disinfect
- relieve pain
- strengthen gums
- inhibit inflammation

The healing process is accelerated if Regulat is sprayed onto the wound after tooth extraction. The risk of infection is also minimised. Inflammation of the gums, aphthous ulcers and other lesions heal within the shortest possible time. Pain in the mouth often disappears directly after rinsing with Regulat for the first time.

Toothache is relieved rapidly if a mouthful of Regulat is rinsed around between the teeth.

Periodontitis and gingival bleeding regress within one or two months as the Regulat strengthens the gums. Recommended use is to rinse between the teeth with a mouthful of RegulatPro® Bio two or three times a day.

Regulat® Dent has been developed especially for oral hygiene. The main component of this mouth rinse is RegulatPro® Bio, the concentrate rich in essential nutrients, with added cranberries, ginger, vitamin C and zinc. The mouth rinse can be used to strengthen the gums, for surgical aftercare following the insertion of implants, and on irritated areas and pressure points. Recommended use is to rinse with 10 ml Regulat® Dent for one minute in the morning and evening.

### **Aphthous ulcers**

Aphthous ulcers are tiny ulcers inside the mouth, which are very painful. Contact with hot or spicy food is particularly bad. They appear as round white patches with red inflammatory margins, measure <1 cm in diameter, and two or three often occur together. They are found particularly on the inside of the lips and cheeks, tongue, soft palate and sometimes even in the throat. In general, they disappear within ten days without leaving any scars. Their origin is unclear; stress seems to be involved. Many of those affected suffer repeatedly from these lesions in the mouth. People with AIDS often have very large, irregularly shaped, aphthous ulcers that persist for many weeks and often cause scarring.

### **How Regulat helps**

- The cascade-fermented bioconcentrate has potent anti-inflammatory effects on the oral mucosa.
- Stimulant effects on cell metabolism and protection from oxidative stress are also beneficial.
- Aphthous ulcers heal within a very short time with Regulat rinses.
- Pain in the mouth often abates after the first

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# Regulat and its uses

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# Regulat and its uses

#### **General instructions for use**

The recommended use of Regulat depends on the precise conditions for which it is to be employed and the nature of the Regulat itself. Since all Regulats are produced by the same cascade fermentation process there are some general instructions for use. In order to develop its full effects, Regulat should be taken regularly for at least three months if the symptoms have existed for some time, i.e. are of a chronic nature.

Regulat acts rapidly in acute situations. No interactions between Regulat and food or medication have been reported. There are no contraindications to their use.

# **Indications for Regulat**

#### Internal use

- Inflammation: joints (rheumatism, gout), internal organs
- Gastrointestinal disease: bloating, irritable bowel, constipation, diarrhoea, heartburn, gastritis and flatulence; also following antibiotic therapy or chemotherapy (to strengthen the gut flora)
- Cardiovascular disease: hypertension, arteriosclerosis
- Chronic fatigue, burnout syndrome, depressive moods, lethargy, exhaustion (RegulatPro<sup>®</sup> Metabolic)
- Allergies: e.g. hay fever, asthma, allergic skin diseases
- Metabolic disorders: hyperlipidaemia, obesity, metabolic syndrome, diabetes (Regulat Special Diet; RegulatPro<sup>®</sup> Metabolic)
- Low immune status: colds, sinusitis, borreliosis (Lyme disease), flu and flu-like infections, infections with fungi, bacteria or viruses

- Acidosis (deacidification, in oxidative stress), for detoxification
- General support in cancer

#### **External use**

- Injuries: cuts, wounds, ulcers, burns, poorly healing wounds, sunburn
- Skin diseases: eczema, atopic dermatitis, psoriasis
- Joint pain
- Skin infections: cold sores, warts, fungal and yeast infections (including vaginal)
- Diseases of the oral mucosa and gums: periodontitis, thrush (candida), aphthous ulcers (Regulat® Dent)
- Nasal conditions: (allergic) rhinitis, sinusitis (nasal spray: diluted 1:3 with water)

#### **Initial aggravation**

In isolated cases, Regulat may lead to an initial worsening similar to the aggravation seen with homeopathic remedies. This is an initial healing reaction. The body tries to make use of what the Regulat has to offer in order to "clean itself up" and get rid of the "rubbish" that has been deposited over the years. There is a flood of metabolic waste which may cause problems. The body then has to get rid of these toxins although its excretory organs are not functioning optimally at this time. This healing reaction usually resolves within a few hours, lasting a few days at most. Patients with hypertension, hyperthyroidism, diabetes mellitus, or who are on anticoagulant therapy, are particularly susceptible. The dose should be reduced if signs of aggravation appear.



# Dosage recommendations for internal use

Regulat for internal use is usually taken in the morning - preferably on an empty stomach - and in the evening just before going to bed. The recommended dose is 10 ml, equivalent to a large dessert spoon, a small liqueur glassful or a large mouthful. Experience with larger doses (up to 100 ml a day) has shown good results in cancer patients. Regulat is a completely natural concentrate. No flavouring, sugar or similar agents are added to improve the taste, which means that it may take a while for some people to get used to it. Regulat can also be taken diluted: 10 ml Regulat can be added to half a glassful of water and drunk slowly. Fruit juice can be used instead of water if necessary. It is a good idea to hold the Regulat in the mouth for as long as possible so that its valuable ingredients can be absorbed into the bloodstream through the oral mucosa.

#### "Alternating therapy"

"Alternating therapy" is used especially for detoxification. It can also be used for the initial treatment of many chronic conditions.

#### Dosage

- 5 ml (1 teaspoonful), in the morning, for 3 days
- 5 ml, mornings and evenings, for 3 days
- 10 ml, mornings and evenings, for 1 week
- 20 ml, mornings and evenings, for 1 week
- 20 ml, in the morning, at midday and in the evening, for 1 week
- 20 ml, mornings and evenings, for 1 week
- 10 ml, mornings and evenings, for 1 week

A daily dose of 20 ml is recommended for maintenance therapy.

### **External applications**

#### **Spray**

Regulat can be diluted 1:1 with water and filled into a spray bottle. It is then easy to spray onto the area where it is needed.

#### **Nasal spray**

For use as a nasal spray, (e.g. with rhinitis or sinusitis) RegulatPro® Bio is diluted 1:3 with water and put in a spray bottle. Each nostril is sprayed several times a day with this solution. The Regulat/water mixture should be sprayed firmly, as high up as possible, so that its effects can develop throughout the nose and sinuses.

#### The RRT method

Another method for the external use of Regulat is the "RRT method". The Regulat is mixed 1:1 with water. Eight cotton wool pads are soaked in the solution and wedged between the toes. A pair of loose, comfortable socks is worn on top. The soaked pads remain in place overnight, which allows their stimulant effects on lymphatic drainage to develop. The RRT method can also be used for several other medical conditions, including the following:

- Sleep disorders
- Loss of drive
- Migraine
- Visual disturbances
- Circulatory disorders
- Bladder problems
- Sciatica



# Use in children and pregnant women

#### Regulat for children

RegulatPro® Bio does not contain any alcohol, sugar or preservatives. It is completely natural and therefore also suitable for children.

#### Regulat in pregnancy

RegulatPro® Bio can be used to support pregnancy. Many pregnant women are lacking in energy as well as having particularly high enzyme and ATP demands. Supporting the regulation processes as well as the energy and enzyme balance with RegulatPro® Bio is particularly beneficial to women at this important stage of their lives.

# The different Regulat products

### RegulatPro® Bio – the original

RegulatPro® Bio is produced by the patented cascade fermentation process. RegulatPro® Bio is a unique enzyme extract with essential amino acids, di-, tri- and oligopeptides, polyphenols, flavonoids, and probiotic components from organically grown fruits, nuts and vegetables. RegulatPro® Bio contains natural vitamin C from acerola extract.

Cascade fermentation produces unique active biological units as precursors for the body's intracellular enzyme production – a natural concentrate that the body can use immediately for its own purposes.

# RegulatPro® Bio – pure nature in a concentrated form

- Supports the biological regulatory processes and balances the enzymes
- Improves the energy supply to the cells, revitalises and invigorates
- Reduces oxidative stress
- Restores the balance of the immune system
- Attenuates tiredness and fatigue

RegulatPro® Bio – naturally free from colourings, preservatives, alcohol, sugar, gluten, milk or flavour enhancers. RegulatPro® Bio is suitable for vegans.

Average nutritional value	pro 100 ml
Energy	92.4 kJ/21.4 kcal
Protein	0.3 g
Carbohydrates	5.1 g
of which sugars	<0.1 g
Fat	<0.1 g
of which saturated fatty acids	<0.1 g
Dietary fibre	<0.1 g
Sodium	0.01 g
Vitamin C	61.25 mg

### RegulatPro® Metabolic

RegulatPro® Metabolic is a nutritional supplement that supports enzymatic processes in the body. RegulatPro® Metabolic contains the concentrated strength of Regulat with its unique enzyme extract, which contributes to restoring the equilibrium of the body's natural functions. Physiologically important nutrients address the body's increased needs.

RegulatPro<sup>®</sup> Metabolic is a nutraceutical to reinforce biological regulatory processes. Neutraceuticals are exceptional cutting-edge nutritional supplements for today's stressed individuals.

# RegulatPro® Metabolic – the cutting edge nutritional supplement

- Has a positive effect on glucose metabolism due to its chromium and zinc content
- Supplies magnesium, manganese and vitamins B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub>, B<sub>6</sub>, B<sub>12</sub> and C for energy metabolism

- Contributes to normal protein metabolism due to its vitamin B<sub>6</sub> and zinc content
- Boosts immunity due to its content of vitamins B<sub>6</sub>, B<sub>12</sub>, C, D<sub>3</sub> and zinc; supports muscle and connective tissue function with vitamins C and D<sub>3</sub>, manganese and zinc
- Is particularly important for the antioxidative protection system by reason of the vitamins B<sub>2</sub> and C, zinc and manganese which it contains
- Helps maintain the electrolyte balance due to its manganese content
- Supports normal muscle and nerve functions due its content of magnesium and vitamins B<sub>6</sub> and B<sub>12</sub>
- Alleviates exhaustion and fatigue by the actions of magnesium, vitamin B<sub>2</sub>, B<sub>3</sub>, B<sub>6</sub>, B<sub>12</sub>, pantothenic acid, folic acid and vitamin C
- Helps with weight loss

RegulatPro® Metabolic – naturally free from colourings, preservatives, alcohol, sugar, gluten, milk or flavour enhancers. RegulatPro® Metabolic is suitable for vegans. A dose of 100 ml is equivalent to 0.8 carbohydrate exchanges.

#### Please note

Not to be used as a substitute for a varied, balanced diet and healthy lifestyle.



Average nutritional value	per 100 ml	Daily dose = 2 x 10 ml
Energy	194 kJ/ 46.4 kcal	38.8 kJ/ 9.3 kcal
Protein	0.64 g	0.13 g
Carbohydrates	10.39 g	2.08 g
of which sugars	5.03 g	1 g
Fat	0.14 g	<0.1 g
of which saturated fatty acids	<0.1 g	<0.1 g
Dietary fibre	1.16 g	0.23 g
Sodium	0.01 g	<0.01 g

Average nutritional values	Daily dose = 2 x 10 ml	% of the recommended daily dose
Magnesium	75 mg	20%
Vitamin C	20 mg	25 %
Vitamin D	5 μg	100%
Thiamine	0.33 mg	30%
Riboflavin	0.42 mg	30%
Niacin	4.8 mg	30%
Pantothenic acid	1.8 mg	30%
Vitamin B <sub>6</sub>	0.42 mg	30%
Folic acid	30 μg	15 %
Vitamin B <sub>12</sub>	0.75 μg	30%
Zinc	10 mg	100%
Manganese	2 mg	100%
Chromium	25 µg	62.5 %

\* Recommended daily requirements according to EU guidelines

### **Regulat Special Diet**

Regulat Special Diet is a dietary supplement intended as part of a balanced diet for people with diabetes. This concentrate, which is rich in essential nutrients, contains RegulatPro® Bio as the main component. With its added components of zinc, chromium, B vitamins and bitter melon, Regulat Special Diet has a beneficial effect on glucose metabolism.

# Regulat Special Diet – for a healthy glucose metabolism

- With 80% RegulatPro® Bio, it supports the biological regulatory processes
- Increases the energy supply to the cells
- Reduces oxidative stress
- Improves immunity
- Improves the blood glucose tolerance factor and insulin storage due to its chromium and zinc content
- Bitter melon has beneficial effects on glucose metabolism
- B vitamins improve energy metabolism and nerve functions

Average nutritional values	per 100 ml	Daily dose = 2 x 10 ml
Energy	178 kJ/ 42.5 kcal	35.6 kJ/ 8.5 kcal
Protein	0.60 g	0.12 g
Carbohydrates	9.47 g	1.89 g
of which sugars	4.97 g	0.99 g
Fat	0.14 g	<0.1 g
of which saturated fatty acids	<0.1 g	<0.1 g
Dietary fibre	1.10 g	0.22 g
Sodium	0.01 g	<0.01 g

Average nutritional values	Daily dose = 2 x 10 ml	% of the recommended daily dose*
Bitter melon extract	250 mg	n.r.
Vitamin C	30 mg	38%
Thiamine chloride- hydrochloride	0.35 mg	32%
Riboflavin	0.4 mg	29%
Niacin	4.5 mg	28%
Ca pantothenate	1.5 mg	25%
Pyridoxine HCL	0.5 mg	36%
Folic acid	0.05 mg	25%
Cyanocobalamine	0.25 µg	10%
Zinc chloride	15 mg	150%
Chromium (III) chloride hexahydrate	0.1 mg	250%

<sup>\*</sup> Recommended daily requirements according to EU guidelines n.r. = no recommendation

### **Regulat® Dent Healthy Mouth**

Regulat® Dent Healthy Mouth is a mouth rinse containing RegulatPro® Bio, the concentrate rich in essential nutrients, as the main component. It promotes vitality of the gums and maintains a healthy oral cavity flora. Probiotic components of RegulatPro® Bio restore equilibrium to the oral flora. Cranberries support oral hygiene, have astringent effects and can protect the teeth and gums. Ginger is well known for its invigorating effects and improves the blood supply to the gums by increasing perfusion. Regulat® Dent Healthy Mouth has anti-inflammatory effects and calms irritated gums.

# Regulat® Dent Healthy Mouth – for healthy gums and beautiful teeth

- Strengthens the gums
- Promotes blood perfusion
- Creates a healthy oral flora
- Regenerates and firms the oral mucosa
- Reduces the depth of periodontal pockets
- Is ideal for postoperative care after oral/dental surgery and implants
- Relieves pain at pressure points and areas of irritation
- Particularly good for children as it is completely natural
- Suitable for prophylaxis with sensitive teeth

Regulat<sup>®</sup> Dent Healthy Mouth – naturally free from colourings, preservatives, alcohol, sugar, gluten, milk or flavour enhancers. Regulat<sup>®</sup> Dent Healthy Mouth is suitable for vegans.

#### Please note

Regulat is completely harmless if swallowed accidentally.

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