

# PROJECT TMAZ

## **SUMMARY OF RESEARCH RESULTS 1997 - 2007**

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# 1. INTRODUCTION

Regarding the latest scientific understanding of human genome and the influence of certain food nutrients (vitamins, minerals, phenols) on variations in genome expression in view of reducing the risk of the appearance of certain diseases, 21<sup>st</sup> century medicine will be based mainly on prevention (prophylaxis) of both acute and chronic diseases.

Today the concept "food as medicine" is already being referred to more and more, and scientists as well as the food industry are oriented towards the creation of new food products with specific functional properties and enriched with nutraceuticals, which help in prevention or in solution of certain health problems.

Other factors thought to contribute to a healthy lifestyle are also recommended, such as physical activity well into old age, avoiding intake of toxic substances (e.g. alcohol, tobacco), as well as diets rich in fibers, vitamins, minerals and other antioxidants.

Megamin/Skalaris Detox, a dietary mineral preparation which has recently appeared on the market, is a food supplement which has generated interest among the scientific and professional community as a result of the surprisingly positive effects that have been noted, particularly with those suffering from severe chronic diseases.

Megamin/Skalaris Detox and its derivations, i.e. various preparations which have been, over the last 8 years, created as combinations of the basic product with other natural substances that have the joint characteristic – they are the combination of special, patented technology for an increase in reactive capacity of mineral raw materials (TMA-technology) and natural zeolit.

The results of scientific investigations of the effects of Megamin/Skalaris Detox, particularly its basic component, tribomechanically activated zeolit – clinoptilolites, in veterinary and human medicine, have shown their strong antioxidative effects, absorption of heavy metals and toxins, as well as bringing patient organism into balance of functions of individual organs as well as the whole body (equilibrium).

In a little over 8 years, through scientific researches and observations of patients in Croatia, Austria, Germany and the United States, valuable data has been collected on the potential effects of this mineral product, which is further elaborated in summary form.



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## 2. ZEOLITE

*Figure 1* Zeolite Mineral



Zeolites are natural micro-porous silicate minerals, ranging from colourless to white or light red possibly with colorations due to the presence of impurities and traces of other minerals. They are Al-Na or Al-Ca silicates in composition, and when heated foams and seems to melt. Their natural environment is volcanic formations and cliffs sediment with gas and steam, as well as oceans. Morphologically there are three basic types:

- a) fibrous Zeolite
- b) leafy Zeolite
- c) crystalline Zeolite

There are 106 different naturally occurring types of Zeolite, and for the tribomechanical processing in the patented machine, the crystalline Zeolite Clinoptilolite, has been selected, mostly because of its characteristics of absorbability, selectivity and ion exchange capacity.

This mineral is completely harmless for humans, which has been demonstrated through chemical analyses and toxicological studies performed by scientists involved in this project.

Industrial exploitation on Clinoptilolite and/or its relative heulandites, is carried out in the southeastern Balkans (around the border between Bulgaria and Serbia), in Russia (Zakavkazje), in France (Nantes), in Cuba, in the USA (Oklahoma, California), while the potential for exploitation is being researched in many other areas.

A Clinoptilolite from the Kozark area, in the village of Nižny Hrabovec near Košica in Slovakia, was selected for the production of TMAZ. The site is over 3 km long and about 100 m wide; while the thickness of the layer averages about 100 m. Reserves are calculated at more than 7 million tons.

Macroscopically, the cliff mineral can be described as a small granular homogenous pale green mass. Flint grains have sharp edges and are completely pure with no visible insertions.




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Microscopically, the mineral is found to contain fresh feldspar and very fine grains of radial Zeolite. It is a typical tuffaceous mineral mainly consisting of volcanic glass, which has been later re-crystallized. The content of Zeolite is determined using x-ray diffraction analysis.



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## 3. ZEOLITE PROCESSING TECHNOLOGY

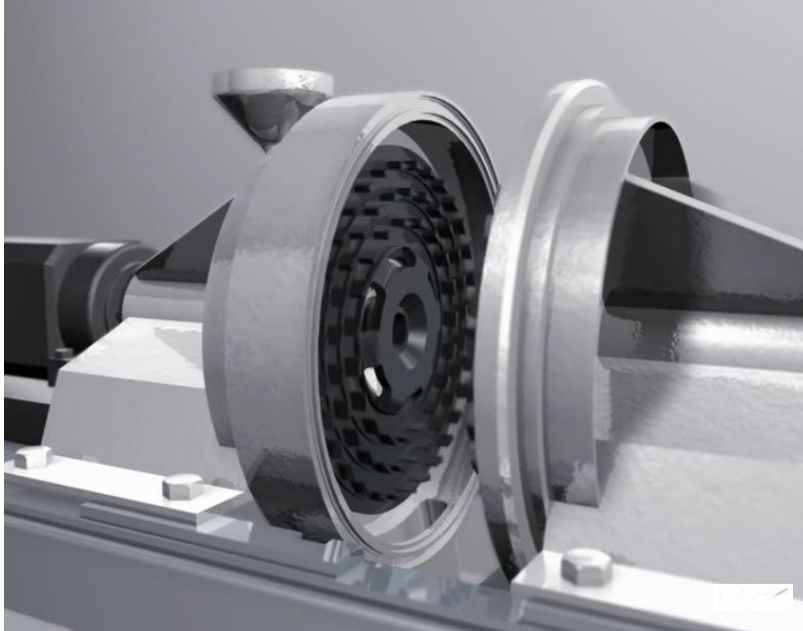
### 3.1. Technology selection

The business strategy of the project is based on implementation of patented technology of tribomechanically micronisation and activation (TMA). Micronisation and activation are induced by friction dynamic process between the contact surfaces caused by great speed in very short time intervals, which is significant invention in the field of processing considering that it is about functional nanotechnology application.

By using specific procedures of tribomechanically micronisation and activation of natural minerals, the effective multifunctional product is produced.

The specific procedure of tribomechanical micronisation and activation has been made possible with the specially constructed and patented machine TMA-desintegrator.

**Figure 2. TMA-desintegrator**



TMA-desintegrator consists of a dismountable housing containing two rotor disks that face each other. The disks are powered by an axle and belt transmission to electrical motors, and turn independently in opposite directions at the same angular rate. Attached to the rotary disks are two or more concentric wreaths with striking

pins and ventilator blades which are constructed and arranged to be able to pass by each other freely while moving in opposite directions.

The disks are also constructed with grooves, which prevent uncontrolled passage of material, which is being processed.

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The purpose of the striking pins and ventilator blades is to create a turbulent flow of air to accelerate the material and increase the collisions and frictions between particles at a particular angle.

The starting materials enter the machine through the central part of the rotor system with suction. The particles are accelerated and adjusting by ventilator air stream and because of the repeated change in motion directions they are in collision and friction in very short time intervals ( $10^{-5}$  to  $10^{-6}$ s). Significant changes in shape and size of particles take place. The relatively movement of one particle along the surface of another in dynamic conditions results in damage to the surface of the particles and a layer of material directly beneath the surface of the particles.

As a result of the above-mentioned interactions during the processing of mineral raw materials, crystal grates of material at the surface of the particles and in the layers directly below the surface, are destroyed or damaged, and therefore partially transformed from a crystalline to an amorphous shape. This results in changes in the physio-chemical and energetic characteristics of the material.



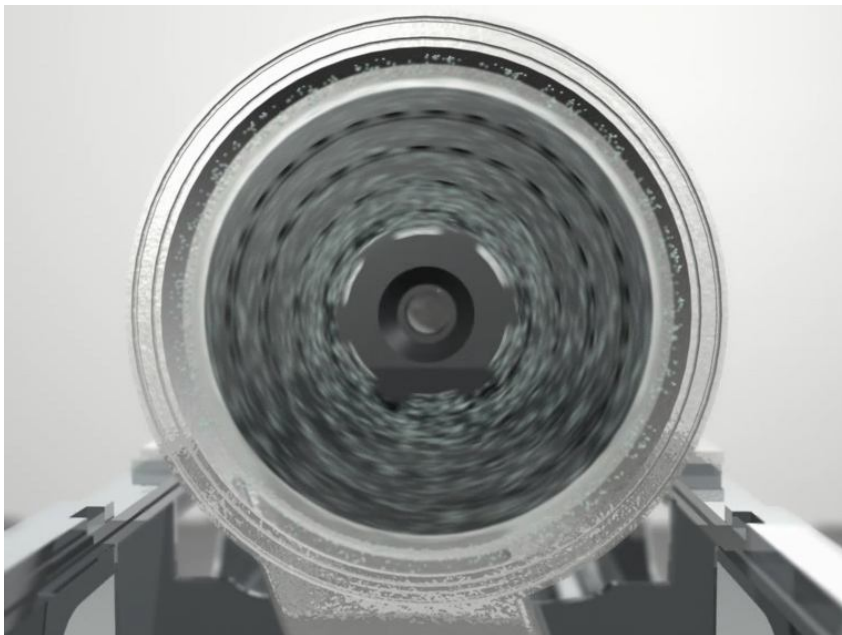
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### 3.2. Description of technological solution

The natural Zeolite (Clinoptilolite) is subjected to fragmentation and repeated collision within the desintegrator (TMA machine) thus changing its physical properties. Not only micronisation of particles to nano size and enlargement of specific area, but also high biological activity (low paramagnetism and increased number of electrons on the surface of particles) are achieved. The size of particles processed in TMA desintegrator ranges from 5 nanometer to 1 micrometer.

Zeolite has a special property of imitating enzymes, which is very important for substance transportation to a cell. Reducing Zeolite to nano size by using TMA technology, that property gets completely new potential on the cell level. Having that fact in mind, along with intensified action of organic substances, this technology will make it possible to use only 10-30 % of certain substances in order to get the same result.



It is important to emphasize that technological segment is the most essential factor of this dietary product, because without such processing of minerals the properties would be unnoticed.

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## 4. PHYSICAL-CHEMICAL CHARACTERISTICS OF TMAZ

The process of tribomechanical activation does not cause changes in the chemical composition of natural mineral Zeolite, which has been determined by x-ray analysis performed on samples before and after the activation.

On the other hand, the tribomechanical activation procedure does alter the physical-chemical properties of natural Zeolite to a significant degree. The most significant changes occur in the particle size, active surface, electro-static charge and ion exchange capacity.

### Particle Size (*supplement 1*):

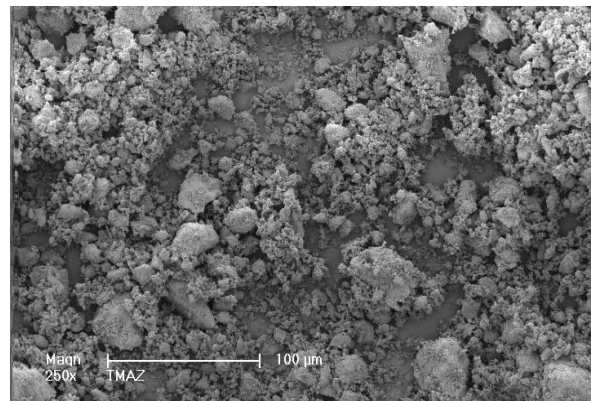
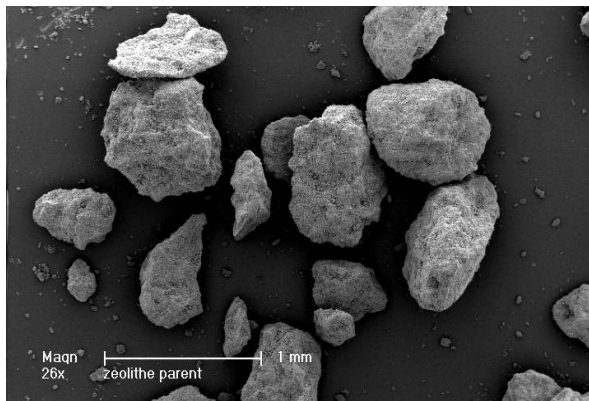
All particles of TMAZ have a diameter less than 83.87  $\mu\text{m}$ .

The average arithmetic diameter is 3.1  $\mu\text{m}$ .

20 % of particles have a diameter less than 1  $\mu\text{m}$

84 % of particles have a diameter less than 5  $\mu\text{m}$

99 % of particles have a diameter less than 10  $\mu\text{m}$



In comparison to Zeolite fragmented by using the classical ball mill method, the average TMAZ particle size is about 20 times smaller.

### Specific Area:



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The specific area is 3,9 m<sup>2</sup>/g, which is about 6 times more than in Zeolite fragmented in the classical way.

### **Electrical Conductivity:**

From the results of electrical conductivity measuring it can be concluded:

- a. TMAZ has greater ion exchange capacity than non-activated Zeolite,
- b. the ion exchange process slows down as time passes,
- c. TMAZ ions are more firmly connected than ions in non-activated Zeolite,
- d. the absolute quantity of ions exchanged increases with a decrease in pH level.

Suspension of TMAZ in water (regardless of the concentration or mixing time) shows a higher pH than suspensions of non-activated Zeolite in water.



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## 5. INVESTIGATED EFFECTS OF TMAZ

Tribomechanically activated Zeolite, or the procedure of tribomechanical activation has already about 10 years, been used experimentally in solving of various problems in agricultural production and construction. In the last few years it has also been proven effective in the treatment of various human and animal diseases, as well as in the production of cigarettes and cosmetic preparations.

### **1) Use in cosmetic products**

Used in cosmetic preparations, TMAZ has been shown to have the following effects:

- direct application of pure powder soothes nettle-rash
- eliminates dandruff by directly applying before washing hair, or mixing in shampoo
- used in skin-peeling applications, either dry or mixed in creams
- helps eliminate wrinkles when applied dry or mixed in creams

### **2) Use in textile industry**

Due to its strong adsorptive, deodorizing and disinfecting action, TMAZ has proven to be very adequate by implementing in textile materials:

- underwear
- socks
- bandages, etc.

### **3) Cigarette production**

It has been proven that TMAZ added to cigarette filters reduces the nicotine content, dry smoke condensate, tar, water and CO<sub>2</sub> in the main current of cigarette smoke. It has also been proven that filters containing more TMAZ have a better flavour and fuller aroma.

### **4) Pharmaceutical Applications**

TMAZ has proven to be very useful (based on anecdotal evidence) in treating the following diseases:



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*a) fighting carcinogenic diseases*

TMAZ has been proven to fight the following *carcinogenic diseases*:

- skin cancer
- cervical cancer
- breast cancer
- ovarian cancer
- prostate cancer
- brain cancer
- cancer of the liver or spleen
- cancer of the small or large intestine
- lung cancer
- stomach cancer
- bone cancer
- stomach cancer
- bladder cancer
- tongue cancer
- thyroid gland cancer

*b) Circulatory System*

- stabilization and optimization of functioning of the circulatory system along with improved blood pressure and reduced varicosity of the veins, reduction of and complete recovery from edema, swollen veins, hemorrhoids, and disappearance of enlarged capillaries.
- strengthening of the heart muscle, acceleration of post heart attack recuperation

*c) Blood Count*

- There was marked improvement in blood count for all those tested along with value correction in respect of raised levels of cholesterol and triglycerides, as well as other substances (hemoglobin)

*d) Digestive System*

- stabilization and optimal regulation of the digestive system, along with elimination of and recuperation from damage or disturbances such as heart-burn, stomach and duodenal ulcers, ulcerous colitis and Crohn's disease
- helps better utilization of nutrients



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*e) Rheumatic Disorders*

- treatment of all types of rheumatic disorders, including arthritis and rheumatic arthritis

*f) Kidney Function*

- diuretic effect and positive influence in improving kidney function
- treatment of kidney infection

*g) Skin Diseases*

- treatment of skin diseases such as: seborrhea, dermatitis, herpes (all types), psoriasis, neurodermitis, decubitus, eczema, vitiligo and others (through per oral intake and external application of powder)

*h) Diabetes Mellitus*

- in most of those tested there was clear stabilization and decrease in the level of sugar in the blood, as well as prevention of consequences of hyperglycemia, such as polyneuropathy, vision and kidneys damages

*i) Endocrine Glands*

- optimization of endocrine gland activity

*j) Wounds and Burns*

- accelerated healing of wounds with direct application of powder
- direct application of powder to minor burns temporarily relieves pain and eliminates skin damage

*k) Periodontosis*

- treatment of periodontosis and elimination of micro-organisms in the mouth with powder applied directly to the gums or as an additive to toothpaste

*l) Improving Skin Quality*

- significantly increasing resistance to various negative external factors including UV rays



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*m) Neuro-psychiatric Effects*

- overall improvement of disposition
- successful treatment of insomnia, neurosis, depression
- aids in the treatment of epilepsy, schizophrenia, Alzheimer's disease, Parkinson's disease

*n) Increasing Endurance*

- increasing endurance in cases of increased physical effort, reduction of lactate caused by increased physical effort

*o) Fungal Infection*

- quick and complete elimination of various fungal infections of the skin (*Candida* and others) and mucous membrane with direct application of powder
- treatment of fungal infections on internal organs, which can result from radiological procedures in combination with antibiotics
- good effects on mikoplasma

*p) Allergies*

- by regulation of immune system, TMAZ helps in cases of various allergies (respiratory, dermatologic, etc.)

*r) Antiviral Activity*

- it works against adeno and entero virus and helps those diseased with HIV and hepatitis

*s) Antibacterial Activity*

- it has bactericide effect on *Escherichia coli* and *Staphylococcus aureus*, as well as bacteriostatic effect on *Pneumococcus* and *Streptococcus*

*t) Immunomodulatory Effect*

- in different cases of disturbed immunity (hypogamaglobulinemia, autoimmune diseases)

*u) Gynecological Discomforts*

- decreased CIN values
- treatment of HPV



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## **6. SCIENTIFIC RESEARCH OF TMAZ (the basic components of Megamin and Skalaris Detox)**

The scientific researches so far have been carried out in two areas:

### **1) studies of the use of TMAZ**

- a. in medicine
- b. in veterinary medicine
- c. in agronomy
- d. in biotechnology
- e. in food technology

### **2) studies of the use of Megamin for medical purposes**

The first researches on the "TMAZ - MEGAMIN" project began in the spring of 1997, first at the Faculty of Food Technology and Biotechnology, University in Zagreb, then at the Ruđer Bošković Institute in Zagreb, and the Faculty of Mining and Geology, University of Zagreb. Other institutions were later included in the research, such as the Faculty of Veterinary Medicine, University of Zagreb, the Faculty of Science, University of Zagreb, the "Vita Nova" Polyclinic in Duga Uvala, the "Svečnjak" Polyclinic in Zagreb, the Humanomed 2 clinical hospital in Villach as well as regional hospitals in Leoben (both in Austria). Dermatological studies were carried out under the control of Dr. Gasser, official expert.

The public very quickly became interested in the positive effects noted in volunteers who had just begun to use TMAZ as well as in those who had been using TMAZ for a longer period of time. With the intention of making the preparation (TMAZ) available to all interested potential users as soon as possible, the preparation was registered as a dietary product. According to the *Regulations on the Propriety of Dietary Foodstuffs (Narodne Novine 46/94)*, dietary products are those prepared using a special process or containing special substances. The same Regulation prescribes standards of propriety in respect of health benefits.

In accordance with the valid regulations, a mineral preparation containing 50 % TMAZ, called "Megamin" was prepared. The name is patented, and an Opinion on its propriety in respect of health benefits (Analytical finding no. 4252/98) was issued by the Centre of Foodstuffs Control, Faculty of Food Technology and Biotechnology on 20 August 1998.

The Opinion was issued for Megamin (skalaris) products in the form of powder and capsules.



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The similar Opinions were shortly followed for the dietary preparations “Megamin Plus” and “Megamin Forte”.

Megamin preparations were tested and registered for release in trade and sales in Austria in January 2000, in Germany in February of the same year and in the Russian Federation in February 2002.

The basic component of Megamin, TMAZ, was recognized as medical, biophysical, active effective means for topical application, so in 2004 it was notified in Germany as a medical product - Wundpulver, powder for wounds. That permit, registered as EC 0197, is valid for the whole European Community.

A year later, TMAZ was also acknowledged as a medical product for per oral use, for the purpose of organism detoxification of ammonia and heavy metals.

The first research results were presented on 30 October 1998 at an internal conference “Study of the complete toxicology of TMAZ preparations and effects on various organic physiological systems” held at the Ruđer Bošković Institute in Zagreb. Summaries of the lectures given have been published in a book of abstracts.

The results obtained, discussions held at the conference and the exchange of experience served as a sign-post for further researches, which are still underway. The results of some of these studies are being prepared for publication in reputable international scientific publications.

**Results obtained so far can be grouped as follows:**

- 1. Study of the physical-chemical characteristics of TMAZ—the basic components of Megamin**
- 2. Examination of the toxicity of TMAZ**



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### **3. Preliminary researches on the effects of TMAZ (in vitro and in vivo)**

- Testing of effect on tumor cells
- Testing of effect on diabetes mellitus
- Immunostimulatory effects
- Testing of anti-oxidative effect
- Testing of adjuvant effect
- Testing of effect on viruses
- Testing of effect on cell receptors
- Morphological and functional changes of micro vascular systems and immune systems of small intestine
- Effect on cell medium and resultant effect on tumor cells
- Testing in cases of intensifying reactive abilities and biological activities in combination with other substances

### **4. Pre-clinical researches**

- Use of TMAZ in various canine tumors treatment (Bedrica)
- Use of Megamin with liver disease treatment
- Use of Megamin in healing wounds (Vučevac)
- Use of Megamin in neuro-degenerative diseases
- Study of the use of Megamin in patients with transitory hypogamaglobulinemia (Žižek)
- Use of Megamin as an adjuvant with malignant and other diseases treatment (Rudeš)
- Anti-oxidative characteristics of Megamin – study at Humanomed 2 clinic in Villach
- Use of Megamin in cancerous diseases (Ivković)
- Use of Megamin after cardio surgical operation – recovery (Russian Research Centre of Surgery)
- Anti-oxidative and hemodynamic effect of Megamin in patients with diabetes and coronary heart diseases (Medical academy Zaporozje)
- Effect of TMAZ on ventricle (Čučkov)

### **5. Clinical studies**

- Clinical testing of TMAZ in immunodeficiency (Ivković et al.)
- Clinical testing of TMAZ in psoriasis (Klinomed - Helios)
- Clinical testing of TMAZ in diabetes mellitus type 2 (Klinomed - Helios)
- Clinical pilot study of effect of TMAZ on prostate cancer
- Clinical pilot study of effect of TMAZ on breast cancer



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## 6.1. INVESTIGATION OF PHYSICAL-CHEMICAL CHARACTERISTICS OF TMAZ

A series of experiments were carried out at the Faculty of Pharmaceuticals and Biochemistry under the leadership of Dr. Stanko Uršić PhD in 1998, with the aim of confirming the individual physical-chemical characteristics of TMAZ. The experiments included:

- a) measurement of the electrical conductivity of suspensions of TMAZ in several acids of various molality depending on the length of mixing time,
- b) measurement of the electrical conductivity of suspensions of TMAZ and various amino acids depending on the length of mixing time at temperature 25°C.
- c) measurement of the electrical conductivity and pH value of suspensions of TMAZ depending on the concentration and length of mixing time,
- d) measurement of the interaction of TMAZ in model reaction of oxidation of L-ascorbic acid/ L-ascorbate with nitrobenzene (measurements were carried out using various liquids and with various concentrations of TMAZ)

The results obtained lead to the following conclusions:

Because of the very high fraction of small particles (nano-particles) it is assumed that one portion of TMAZ particles enters an organism's gastro-intestinal tract where they can participate in:

- a shift in pH value in and near the cells (e.g. a decrease in acidity in tumor cells whose pH is regularly low can have an anti-tumor effect; possible inclusion in oxidation processes in mitochondria – Bohr's effect),
- selective transfer of amino acids (e.g. thyroxin), peptides, oligonucleotides,
- changes in the functioning of the ionic pump due to ionic exchanges combined with adsorption of nano-TMAZ particles on the cell membranes
- interactions with cell receptors, thereby influencing processes within the cells,
- anti-tumor defense of the organism due to occasional or complete blockage of carbo-cations and free radicals. It is also possible that they participate catalytically in the decomposition of cancerogenic agents
- synergetic transfer of bio-active molecules



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## **6.2. TESTING THE TOXICITY OF TMAZ (*supplement 2*)**

Testing of the toxicity of TMAZ was performed in 1998 and 1999 at the Ruđer Bošković Institute, Department of Molecular Medicine under the leadership of Dr. Krešimir Pavelić PhD, and included:

- a) testing of acute, sub chronic and chronic toxicity of TMAZ
- b) toxicity of the preparation in reproduction and development of the organism
- c) non-clinical testing of localized tolerance (eyes, skin) to the preparation
- d) genetic toxicology
- e) 90 day testing of oral toxicity in mice

### **a) ACUTE, SUBCHRONIC AND CHRONIC TOXICOLOGY**

This study can be divided into several groups:

#### **Testing of toxicity in mice**

##### **1-A "LIMIT" test**

Mice (males) were given TMAZ orally in daily doses from 400 to 1000 mg, for 6 to 30 days. Not one mouse died during the "limit" test. From the results obtained, it can be concluded that TMAZ is completely non-toxic in male mice.

##### **1-B "UP AND DOWN" test**

Male and female mice were given TMAZ orally in daily doses from 60 to 400 mg over a two week period. The total dosage given to these mice ranged from 0.84 to 5.60 grams. Not one mouse died in the experiment. From the results obtained, it can be concluded that TMAZ is completely non-toxic in male and female mice.

##### **1-C Acute, sub chronic and chronic toxicology in mice**

The aim of this study was to determine the toxicity of the preparation in male and female mice over a period from 1 to 6 months. TMAZ was given in a diet (TMAZ mixed with standard food at the ratio 25:75 ). Study of acute, sub chronic and chronic toxicology included determination of the following parameters:



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- body weight
- quantity of food and water consumed
- weight of feces
- urine clinical chemistry parameters (specific gravity, glucose, bilirubin, erythrocytes, leukocytes, pH, proteins, urobilinogen, nitrites)
- phenotypic and behavior changes
- clinical laboratory study (after 30 days, after 3 months, after 6 months) which included:

- *hematological testing:*

number of leukocytes (total and differential), number of erythrocytes, number of thrombocytes, haematocrit, hemoglobin concentration

- *clinical chemistry*

glucose, inorganic phosphorus, calcium, bilirubin, alkaline phosphates, aspartate aminotransferase, alanin aminotransferase

- necroscopy – post mortem evaluation of killed mice after 30 days, after 3 months and after 6 months
- microscopic pathology
- mortality

The results of these studies have shown that there were no differences between mice who had taken TMAZ and mice from the control group during the entire period of 6 months. The conclusion drawn was that TMAZ is entirely non-toxic in mice.



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### **Testing of toxicity in rats**

#### *Acute, sub chronic and chronic toxicology*

The aim of these studies were to determine the toxicity of TMAZ in male and female rats over a period from 1 to 12 months. The rats were divided into three groups: one was a control group, the second one was given food containing 25 % TMAZ, and the third one was given food containing 50 %TMAZ.

Study of acute, sub chronic and chronic toxicology included determination of the following parameters:

- body weight
- quantity of food and water consumed
- weight of feces
- urine clinical chemistry parameters (specific gravity, glucose, bilirubin, erythrocytes, leukocytes, pH, proteins, urobilinogen, nitrites)
- phenotypic and behavior changes
- clinical study (after 2 and 3 months for sub chronic toxicology; for acute toxicology, after 5, 7 and 12 months for chronic toxicology)
- laboratory study (after 15 and 30 days)

- *hematological testing:*

number of leukocytes (total and differential), number of erythrocytes, number of thrombocytes, haematocrit, hemoglobin concentration

- *clinical chemistry*

glucose, inorganic phosphorus, calcium, bilirubin, alkaline phosphatase, aspartate aminotransferase, alanin aminotransferase

- necroscopy – post mortem evaluation of killed mice after 30 days (at acute toxicology), after 2 months and after 7 months (at sub chronic toxicology), after 12 months at chronic toxicology
- microscopic pathology
- mortality

The total daily dosage of TMAZ given to the rats has been calculated into the potential dosage of TMAZ for human beings (based on body weight of 75 kg with a factor of 7 which takes into account differences in human and rat metabolism). These calculations are shown in the following table:

**Table 1:** TMAZ Dosages in Rats Calculated for Human Consumption



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	Acute (g/day)	Sub chronic (g/ day)	Chronic (g/day)
25 % rat	4,8	4,0	3,3
25 % human	230	190	167
50 % rat	12,1	9,7	7,8
50 % human	614	490	390

*Acute toxicology:* Results have shown that there was no difference between the animal control group and the animals who were given TMAZ.

*Sub chronic toxicology:* Results have shown that there was no difference between the control group of rats and the group that was given TMAZ, which means TMAZ is completely non-toxic.

*Chronic toxicology:* Results have shown that there was no difference between the control group of rats and the group that was given TMAZ, which means TMAZ is completely non-toxic.

Based on the results of the study in which rats were given TMAZ in quantities from 3.3 to 16.0 g/rat/day over a period of 12 months, it can be concluded that TMAZ did not induce any changes in rats.

### **b) TOXICITY OF TMAZ IN REPRODUCTION AND DEVELOPMENT OF ORGANISM**

A number of experiments were performed on a few pairs of mice that were given TMAZ mixed with food, before and during pregnancy, in order to investigate toxicity of TMAZ in the reproductive cycle.

The results obtained have shown that TMAZ did not induce any toxic changes in the mice, in the reproductive cycle, or in the organo-genetic phase.



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### **c) NON-CLINICAL TESTING OF LOCALISED TOLERANCE TO TMAZ**

Tests were performed on mice and rats, such that TMAZ powder or suspension was directly applied to their eyes, and TMAZ powder or cream to their skin.

The results from testing on eyes showed that there were no macroscopic changes in the eyes, but that TMAZ can cause irritation to the eyes, most likely due to mechanical damage.

The results of testing on the skin showed that no macroscopic or microscopic changes were induced in the skin, in the rats or the mice. This means that TMAZ does not induce irritation or urticaria in the skin.

### **d) GENETIC TOXICOLOGY**

The study of mutagenesis, was carried out against the Ames method, and therefore the bacteria *Salmonella typhimurium* His species TA98 and TA100 was used. The results demonstrated that TMAZ contains no mutagenetic activity.

### **e) 90 DAY TESTING OF ORAL TOXICITY IN MICE**

The testing was performed in 3 test groups and 1 control group. The mice in the test group were given experimental substance over a period of 90 days. The animals were observed twice a day from the aspect of morbidity and mortality, and once a day from the aspect of pharmacological and toxic effects. After 90 days of application in concentration of 200-2000 mg/kg no signs of intoxication in mice were found.



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### 6.3. PRELIMINARY STUDY OF TMAZ ACTIVITIES (in vivo and in vitro)

Preliminary researches were carried out at the Ruđer Bošković Institute in the period between November 1997 and March 1998 with the aim of establishing conditions for carrying out pre-clinical testing of TMAZ, testing of its potential therapeutic effects as well as performing a thorough study of its toxicology.

- Testing of effects on diabetes mellitus (*supplement 3*)

Investigations were carried out on mice, who 7 days after being induced with diabetes mellitus were fed for 14 days with 50, 100 or 200 mg of TMAZ per mouse. The result was restoration of body weight to an even slightly greater degree than in the control group, as well as improved glucose tolerance, which normalized after only 2 hours following injection of 1 g of glucose per kilogram of body weight. Not one of the doses studied produced a hypoglycemic reaction.

- Testing of effect on tumors *In vitro* (*supplement 3, 4, and 5*)

Tests were run on the influence of TMAZ on the inhibition of growth in MiaPaCa2 tumor cells (human pancreatic carcinoma), HeLa (human cervical carcinoma) and Hep2 (human laryngeal carcinoma). Results showed that inhibition of cells growth occurred dependant on the dosage of TMAZ used and the type of tumor. The most effective dose proved to be 50 mg/ml, and the best effects were noted with MiaPaCa2 cells.

Effect of TMAZ on cell growth after direct treatment of cells

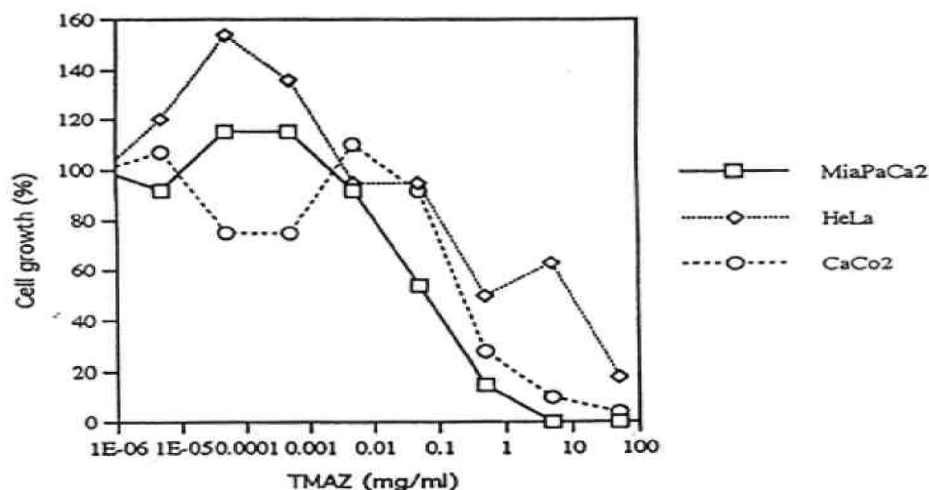


Figure 3: Effect of TMAZ on cell growth after direct treatment of cells



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### ***In vivo***

Mice were inoculated with melanoma B16 cells, and were then given TMAZ twice a day orally for 5 days. Observation of tumor volume confirmed that TMAZ reduced tumor volume in mice.

In another parallel research performed at the University in California the effect of Megamin was tested in three groups of human cells: HeLa, CaCO-2 and HT-29. Inhibition of growth was noted in the all three groups when Megamin was used in pre-tested medium.

While testing molecular mechanisms of anti carcinogenic activities (*Journal of Molecular Medicine*) of natural dietary products, it was observed that strong antioxidants can modify activity of one or more proteins kinase in the cell cycle. When micronized Zeolite was applied, different proteins kinase are activated or deactivated. That happens directly or indirectly through a few transcription factors such as NF-IL6 or tumor suppressor gene such as p21 and p27.

Besides the mentioned ones, the testing of the influence of the previous procedure of effect of TMAZ on efficiency of cancer cells destruction was performed as well, and results are shown in the **table 2**.

**Table 2** Degree of effect (%) of TMAZ on cancer cells

Cell culture	Degree of effect (%)	
	from	to
Cells V79 (fibroblasts of hamster)	44,0	64,0
Cells of cervix carcinoma	70,0	93,0
Cells of breast carcinoma	27,0	46,0

As it can be seen, the greatest efficiency in cancer cells destruction TMAZ manifested in cervix carcinoma, and significantly less in breast carcinoma. The degree of effect considerably depended on the previous processing of TMAZ and it was specific for each cell culture.



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- Immunostimulatory effect (**supplement 6**)

Micronized Zeolite applied by gastric intubation in mice with melanoma cells significantly reduced the number of metastases. In mice fed with micronized Zeolite in the period of 28 days, concentration of lipid connected siliceous acids was increased in serum, but lipid per oxidation in liver was decreased. Also, lymphocytes from lymph knots caused much stronger GVH reaction than in the control group. After application of Zeolite, the number of peritoneal macrophages as well as their production of superoxide anions was increased. In spite of that, generation of nitric oxide did not occur. At the same time, translocation of p65 in the nucleus of spleen cells was observed. It is assumed that micronized Zeolite acts on activation of macrophages which produce TNF- $\alpha$  which, together with other activators (cytokines, ROS and changes of Ca concentration) stimulate spleen T-cells.



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- Testing of anti-oxidative effect (**supplement 7,8**)

-By observing activities of three anti-oxidative enzymes (SOD, GPx, GR), it was found out that TMAZ inhibited radicals (cation ABTS) proportionally to its concentration. The test was carried out on 45 patients, 22 healthy ones and 18 with malignant diseases. FRAS measurement system was used because it enables to evaluate all hyper oxides in blood. Results obtained indicate that TMAZ is a new antioxidant and it seems that its effect is extremely stronger than that of all known so far.

-In the second study 114 patients with carcinogenic diseases and 62 with diabetes were tested. Radox total antioxidant status (TAS) system was used to ascertain the level of superoxide dismutase, glutathione peroxidase and glutathion reductase. The results obtained showed strong anti-oxidative effect of TMAZ and its ability to decrease oxidative stress in patients with carcinogenic diseases and diabetes.

- Testing of adjuvant effect (**supplement 9**)

This testing proved that the treatment with TMAZ increased levels of p21 and p27 in tumor cell models. It was also ascertained that TMAZ combined with doxorubicin acted synergistically, but decreased oxidative stress caused by doxorubicin as well.

- Testing of effect on viruses (**supplement 10**)

According to the research performed at the Ruđer Bošković Institute, micronized Zeolite was capable of inhibiting proliferation of the virus type HSV1, coxsackievirus B5 and echovirus, while adenovirus was inhibited more slightly. Antivirus effect of TMAZ is unspecific and probably it is based on incorporation of virus particles in Zeolites pores than on ion exchange. The preliminary results show the possibility of therapeutic application of TMAZ locally against herpes virus or orally in the case of adeno and entero viruses.

- Testing of effect on cell receptors (**supplement 11**)

Results of testing performed at the Klinomed Institute show that anti carcinogenic activity of TMAZ is not only due to its ability to remove free radicals but also due to direct modulation of cell signals transfer ways.



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- Morphological and functional changes of micro vascular systems and immune systems of small intestine (**supplement 12**)

These morphological studies indicate that Megamin nano particles have direct effect on lymphoid tissue of small intestine, resulting in widening lymph ducts and greater activities of macrophages.

- Effect on cell medium and resultant effect on tumor cells (**supplement 13**)

The aim of this testing was to define effect of TMAZ in cell medium on cell vitality and activation of crucial proteins which regulate cell survival, division and response to stress. After application of TMAZ, the number of functional cells, DNA synthesis and activity of EGF-R, PKB/Akt and NF/B were decreased, while apoptosis was increased. It is assumed that cationic exchange probably influences the levels of calcium and signal ways dependant on calcium within a cell. All these pieces of information demonstrate that TMAZ influences cell microenvironment through mechanisms which depend on adsorptive and ionic exchangeable characteristics of this material.

- Testing in cases of intensifying reactive abilities and biological activities in combination with other substances (**supplement 14**)

The aim of this testing was to ascertain ability of TMAZ as an intensifier of reactive capacities of organic components, as well as increase of their biological availability. A few kinds of substances were tested: TMAZ and TMAZ combined with pollen, nettle and lycopene.

Results obtained showed exceptional synergy and intensifying of probiotic (TMAZ with nettle) and anti-oxidative (TMAZ with lycopene) effects, which leads to the conclusion that TMAZ really intensifies capacities of organic substances.



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## 6.4. PRE-CLINICAL RESEARCHES

- Use of TMAZ in various canine tumors treatment (**supplement 3**)

The effects of using TMAZ for various canine tumors was tested at the Faculty of Veterinary Medicine in Zagreb under the leadership of Dr. Ljiljana Bedrica PhD. Tests were performed on 51 dogs. Before the treatment all the dogs received clinical examinations along with appropriate hematological and biochemical analyses. TMAZ was given to the dogs orally, while affected skin areas were sprinkled with powder.

a) Mammary gland tumors were tested in 10 females between 6 and 14 years of age. The best results were noted in Mammary adenocarcinoma. Smaller tumors disappeared after 3 to 4 weeks of taking TMAZ, while larger tumors reduced in size by half after 4 weeks. Mixed mammary gland tumors did not decrease in size even after 3 months but did not increase in size either. One year after the removal of such tumors there were no signs of recurrence.

b) Tumors of the skin and mucous membrane were tested in 10 dogs between 6.5 and 13 years of age. After receiving TMAZ for a certain period of time, all formations disappeared, but appeared again after TMAZ intake ceased. One week after TMAZ intake was resumed the formations decreased in size once again.

c) Prostate tumors were tested in 6 dogs. Within one week of receiving TMAZ symptoms completely disappeared.

d) The influence of TMAZ on lymphoma was tested in 8 dogs. All the dogs perked up after receiving the preparation for 3-4 days, and after one week were behaving normally. Their blood count was normal one month later.

e) Lung tumors in 3 dogs decrease in size by 50 after one month. Two dogs lived another year, and one that received the preparation irregularly died after three months.

f) Bone cancer was diagnosed in 3 dogs, one of which died two months following the diagnosis, and 2 of which have been receiving TMAZ for a year and a half now.

g) With various other tumors, it was confirmed that in all dogs there was an improvement in overall condition.



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- Use of Megamin in liver disease treatment (**supplement 15**)

In 20 patients with chronic viral hepatitis, with already small doses of 6 capsules per day, fatigue and flatulence were alleviated after two weeks, and after one month there was a reduction in transaminase in the blood (AST, ALT, GGT, AP) and bilirubin. Markers of hepatitis were not found in the DNA and RNA of the majority of patients.

In decompensated cirrhosis, significant improvement in overall condition and retreat of ascites was observed after only 7 days of Megamin taking.

- Use of Megamin in healing wounds (**supplement 26**)

In 1998 studies were performed to determine the potentially favorable effect of TMAZ (active substance in Megamin) on the healing process in superficial skin wounds. Tests were carried out on 30 patients suffering from the following:

*a) acute skin problems* (mechanical skin damage, abrasions, insect bites, post-operative wound treatment, herpes simplex and herpes zoster)

*b) chronic skin problems* (various skin infections, allergic reactions, degenerative diseases, neurodermitis, ulcer cruris, ulcus decubitalis, gangrene of the foot.

TMAZ was applied directly to the wounds once or twice daily. In all the above-mentioned acute skin problems, the wound disappeared completely after a period of 5 to 15 days.

Decubitus ulcers in the sacral and gluteus areas and on the heels in 3 patients healed over 15 to 20 days (on the surface), and deeper wounds in patients suffering from paralysis healed in about 4 months. Chronic ulcer cruris having previously lasted from 2 to 3 years, healed in 2.5 to 4 months.

In patients with circulatory chronic shin ulcers lasting 15 years, within 6 months of observation the wound shrank by more than 50 % along with a clear increase in surface epitelisation and decrease in depth of the wound.

The cases described indicate the favorable effects of TMAZ (and, therefore, Megamin) in the healing of wounds and reversal of pathological skin processes in the skin.



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- Use of Megamin in treatment of degenerative neural diseases (**supplement 15**)

Very favorable effects of Megamin (TMAZ + activated dolomite) have been noted in multiple sclerosis in early phases of the illness. In the terminal phase, with a centre already developed in the brain, results were far more modest. Favorable effects were also noted in neurodermatitis and muscular dystrophy, also in early phases of the disease.

- Study of the use of Megamin in patients with transitory hypogamaglobulonaemia (**supplement 16**)

Study of the use of Megamin in four 3-year-old boys and in one patient aged 40 with transitory hypogamaglobulonaemia (THI) was carried out.

All subjects were given Megamin continually for six months in daily doses 2.4 g (8 capsules á 300 mg).

Before treatment all patients had a low concentration of serum IgG, IgA, and IgM for at least 2SD below the recommended value for their age. They also had lowered reactivity of T and B lymphocytes on mythogenic PHA, Con A and PWM, lowered hemoglobin and haematocrit level in comparison to the recommended level for their age. Level of nourishment was below 50 PCT.

After 6 months of taking Megamin, there was normalization of all observed laboratory parameters, which reached normal levels relative to age. These were hemoglobin, haematocrit, iron, liver enzymes, especially LDH, immunoglobulin's IgG, IgA, IgM, and response to mythogenic PHA, Con A and PWM along with the level of auxiliary cells CD3, CD4 and CD8.

The children were regularly vaccinated without any complications, disease recurrence was significantly reduced and each child reached height and weight in appropriate for their age in accordance with Harvard PCT tables for body weight.

- Use of Megamin as an adjuvant in malignant and other diseases treatment (**supplement 17**)

In early May 1999 at the Regional Hospital in Leoben, Dr. Dražen Rudeš began giving Megamin to 30 patients, 15 of whom had critical malignancies, the The patients with malignancies were suffering from carcinoma of the head and neck, primary or recurring genesis. An accompanying symptom, besides remainder of whom were suffering from neurological illnesses, diabetes, a few Downs Syndrome cases, and a few patients with intermediate to critical neurovegetative dystonia. tissue necrosis, was heavy bleeding that was not possible to treat surgically and conventional medicine had no effect. Then Megamin powder was applied directly to the affected area.



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The bleeding stopped, in principle, after one hour, and after a few days the metastases had decreased by 50, while the smaller metastases had disappeared. All patients gained weight and were able to sleep better. In two documented cases of Multiple Sclerosis there was already significant improvement in the second week of taking Megamin.

Young patients with neurovegetative dystonia reacted particularly well to Megamin treatment. Their appetite returned to a significant degree, serological samples normalized, and in one 13-year-old boy there was normalization in the growth hormone which had been considerably suppressed in the preceding years.

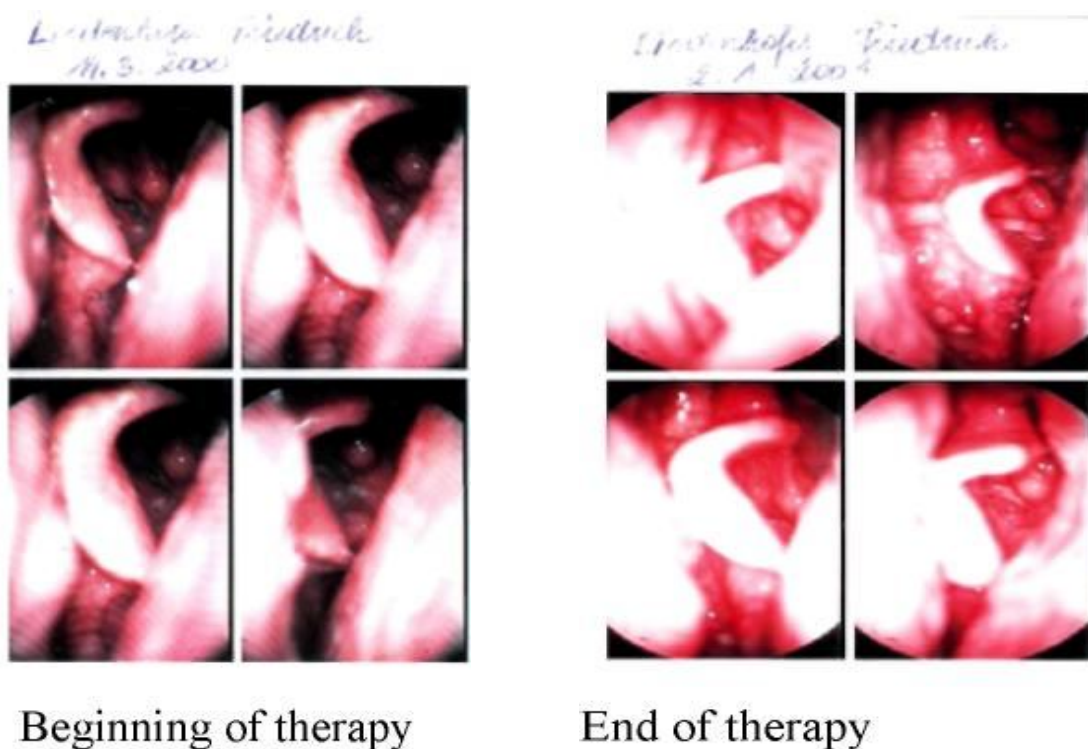
In 2000 and 2001 Dr. Rudeš observed the effects of Megamin in another 20 patients, of whom 15 had cancer.

Besides the already confirmed effects on improvement of overall condition and better endurance through standard methods of treatment, there was a significant case of a patient with developed cancer of the larynx who had refused surgery and standard methods of conventional medicine and who chose to be treated only with Megamin at his own risk. The patient took 16 capsules and 4 spoonfuls of Megamin powder daily for a period of 9 months during which the tumor decreased significantly, from the diameter of 10.0 mm to 3.0 mm, and changed morphologically such that it stabilized and became inactive. On the **Figure 4** are shown photos of tumor on the beginning and on the end of therapy.



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**Figure 4.** Photographs of larynx tumor at the beginning and end of therapy  
 • Anti-oxidative characters of Megamin (**supplement 18**)

It is believed today that free radicals are the main factors of many pathological changes in organisms. It was found that even 90 % of various diseases are result of disturbances in cell function or cell damage caused directly or indirectly by the activity of oxygen free radicals. Organisms defend themselves against free radicals, beside their own defense mechanisms also with natural antioxidants, which are taken into the body with food.

Total Antioxidant Status (TAS) method, which measures the concentration of antioxidants in the organism, seems to be very effective for estimating the condition of antioxidant defense system, as well as a parameter for determining the optimal antioxidant treatment.

This method was used in the Vita Nova Polyclinic in Duga Uvala on a random sample of healthy and ill subjects. The results obtained showed a satisfactory correlation between the TAS value and the number of Megamin capsules taken by the patient.

Regular measurement found out that all patients who had taken Megamin had reached a significantly high TAS value, which was in the upper range of values considered satisfactory.

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In healthy subjects who did not take Megamin, the TAS value varied between 1.22 and 1.65 depending on biological differences, living conditions, dietary habits and other external influences. The remaining healthy subjects, who took Megamin regularly, had significantly higher TAS values.

It is indicative that patients who were suffering from chronic incurable illnesses and for whom a low TAS value would be expected, had, with regular use of Megamin, significantly higher TAS values when compared with the patients who did not have the above-mentioned diagnoses. This indicates that Megamin has an influence on the improvement of the overall condition of organisms and increases their immunity to external influences through mechanism of anti-oxidative activity.

Studies on the effects of Megamin on TAS value in the private Humanomed 2 Clinic in Villach under the leadership of Dr. Wolfgang Thome began in October 2000 and is still underway. 120 patients have been divided into three groups, and the anti-oxidative, immunomodulatory and antiviral activity of Megamin is being observed. Control TAS measurements have been carried out on healthy subjects, a group of 30 volunteers, over a 30-day period. The results are shown in the **table 3** and **figure 5**.

#### Results of TAS measurements

Name of person	Value on the beginning	Values after 2 weeks	Improvement ( % )	Values at the end	Improvement after 3 and 4 weeks ( % )	Improvement of TAS values ( % )
Pilgram Bettina	1,07	1,48	38%	1,48	0%	38%
Klammer Johanna	1,40	1,52	9%	1,52	0%	9%
Kofler Annelies	0,99	1,05	6%	1,07	2%	8%
Krawina Elisabeth	1,24	1,24	0%	1,28	3%	3%
Krassnig Walpurga	1,20	1,48	23%	1,52	3%	26%
Mersal Brigitte	1,39	1,44	4%	1,50	4%	8%
Hock Ursula, Dr.	1,44	1,39	-4%	1,48	7%	3%
Strauß Carmen	1,40	1,46	4%	1,58	8%	12%
Speiser Monika	1,29	1,26	-2%	1,37	9%	7%
Sammer Ingrid	1,22	1,24	2%	1,35	9%	11%
Krug Eduard	1,46	1,67	14%	1,84	10%	24%
Maier-Zanker Karin	1,28	1,30	2%	1,44	11%	13%
Gasser Johannes	1,50	1,69	13%	1,93	14%	27%



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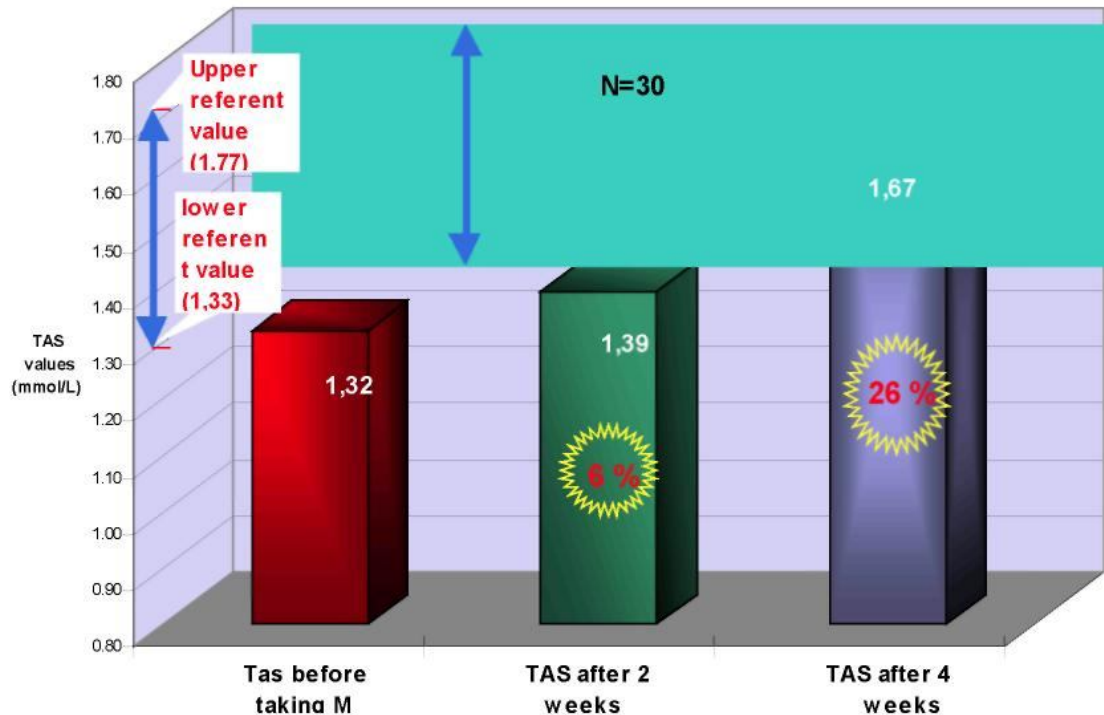
Köfer-Krepler Eva	1,51	1,36	-10%	1,59	17%	7%
Pfeifhofer Josefine	1,24	1,21	-2%	1,43	18%	16%
Schumi Christa	0,97	1,43	47%	1,69	18%	65%
Boiseau Gertraud	1,35	1,59	18%	1,90	19%	37%
Mandl Johann	1,59	1,67	5%	2,01	20%	25%
Tschawuschnig Angelika	1,25	1,35	8%	1,67	24%	32%
Sange Charlotte	1,39	1,21	-13%	1,51	25%	12%
Weißbach Sandra	1,31	1,24	-5%	1,56	26%	21%
Anichhofer Barbara	1,29	1,33	3%	1,70	27%	30%
Frank Rainer	1,36	1,37	1%	1,75	28%	29%
Stefanschitz Agnes	1,25	1,28	2%	1,71	34%	36%
Jost Sascha	1,43	1,33	-7%	1,82	37%	30%
Kiss Christa	1,26	1,40	11%	1,92	37%	48%
Schützenhofer Marion	1,41	1,52	8%	2,10	38%	46%
Mandl Luise	1,36	1,46	7%	2,07	42%	49%
Schützenhofer Justine	1,31	1,39	6%	2,01	45%	51%
Zermann Gerda	1,41	1,43	1%	2,30	61%	62%
Average TAS value	1,32	1,39	6%	1,67	20%	26%



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**Improvement of TAS values at healthy persons treated with Megamin after 2 and 4 weeks  
(12 capsulas of 400mg/day)**



**Figure 5.** TAS values of healthy persons after taking Megamin for 2 and 4 week

From the presented results is shown that Megamin influenced an increase in TAS value of more than 26 % , which is in comparison to known tested antioxidants (A,C, E vitamins, flavonoids, melatonin, etc.) 8 to 12 times more effective.

Monitoring of the group of 120 patients over 14 months has lead to the following results:

- roborant activity was confirmed already after 3 to 5 days of Megamin treatment; a positive response having been given by at least 70 % of patients
- endurance of standard therapies is at least easier; overall condition of patients was significantly improved
- in viral infections, reduction in viral titre in the patients' blood was observed; in patients suffering from hepatitis C regeneration of the liver no further presence of the virus in the liver was detected



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- it has been concluded that Megamin is a substance with very strong roborant and adjuvant qualities which improve the effectiveness of standard therapies and shorten the period of recovery from serious illnesses
- Use of TMAZ in patients with cancerous diseases (**supplement**)

#### *Studies on tumor patients in the USA*

Testing was carried out on five male patients between the ages of 50 and 70 suffering from: prostate cancer, liver cancer, Crohn's disease, intestinal cancer and lung cancer. All patients took TMAZ in capsule form, and after a very short period of time, and in all patients, there was significant improvement in overall condition, increased body weight, as well as disappearance of symptoms.

#### *Studies on tumor patients in Croatia*

a) Testing was carried out on 5 patients (2 female, 3 male) between the ages of 35 and 77, all in critical condition. One female patient was diagnosed with *hypernephroma lat.sin*. The patient refused surgery and chemotherapy, and was in very poor physical and psychological condition. She began taking TMAZ and after a short period of time her overall condition significantly improved, she gained weight and began to walk (which she had previously been unable to do). Another female patient was diagnosed with cervical cancer with metastasis in the bones. After two rounds of chemotherapy she began taking TMAZ in capsule and powder form, which resulted in a 50 % reduction in the tumor and significant improvement in overall condition.

The male patients were suffering from *lymphosarcoma femoris l.sin*, *multiple metastases*, pancreatic cancer and intestinal cancer with metastasis. All began taking TMAZ in capsule and powder form in large doses (24-40 capsules) which quickly resulted in significant improvement in overall condition.

The testing performed demonstrated justification for the need to carry out the remaining pre-clinical tests, particularly testing acute, sub chronic and chronic toxicity.

b) In Croatia in 1998 and 1999, a large number of patients suffering from malignant diseases were observed as they took Megamin under doctors' supervision. The patients were under the supervision of Dr. Slavko Ivković and Dr. Damir Žabčić and were observed and examined at the Svečnjak Polyclinic in Zagreb and the Vita Nova Polyclinic in Umag.

Megamin was taken under medical supervision by a total of 280 patients, and its effects on the overall condition were followed in 114 patients.

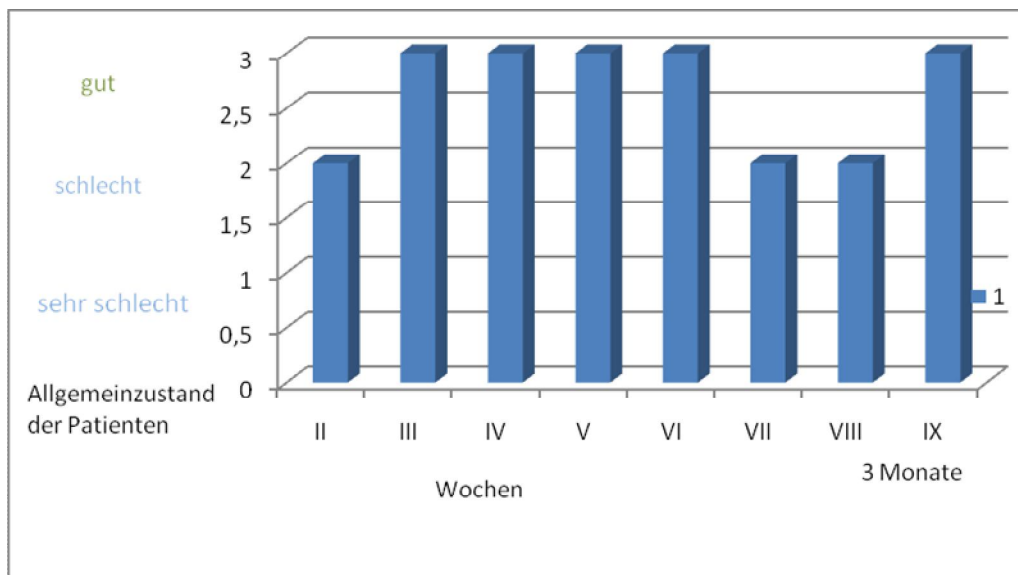
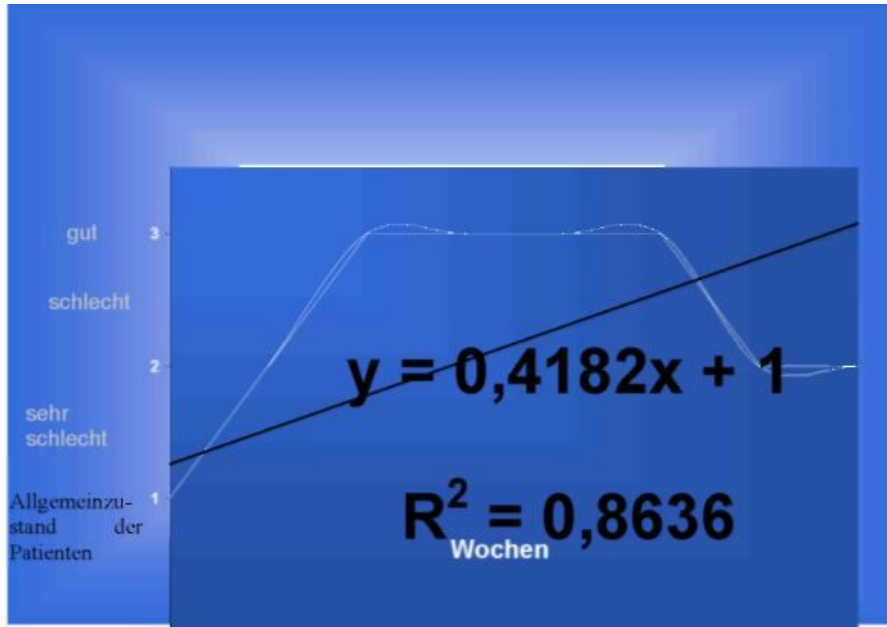
Overall condition and mobility were observed in 21 patients with brain tumors, whose overall condition was weak, who were in the terminal phase of illness,



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mainly immobile and who were receiving symptomatic therapy. After taking Megamin for a period between 3 and 4 weeks, there was visible improvement, such that most of the patients no longer had EPI attacks, they became mobile with assistance, and some of them were capable of reading newspapers on their own and watching television (**Figure 6**) in the second month.



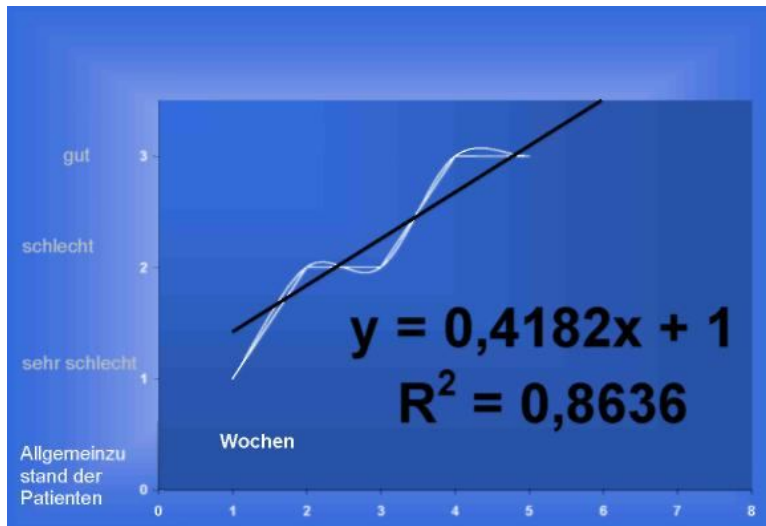
**Figure 6.** Overall condition of patients with brain tumors in relation to length of time of taking Megamin

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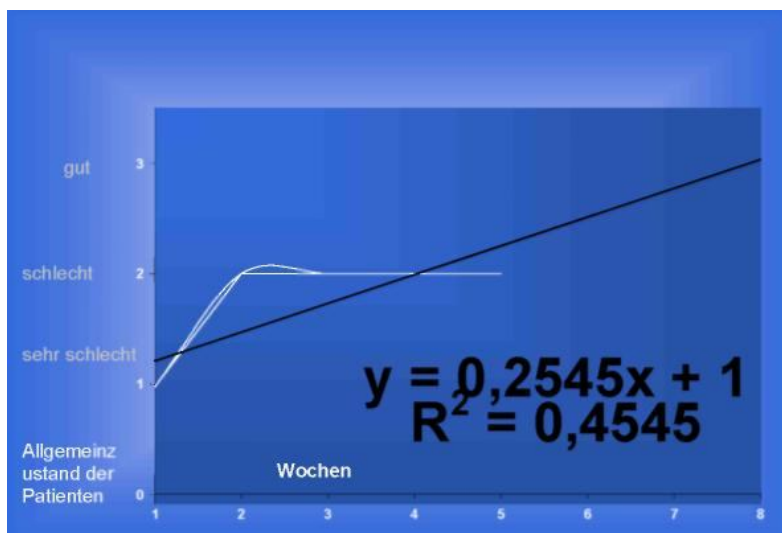
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In 40 patients with primary lung tumors in the terminal phase of illness, improvement of overall condition was noted after 3 to 4 weeks of taking Megamin, pain had decreased, and respiration and mobility had improved. Only one patient, who died in the third week of taking the preparation, rapidly went into an invasive cachectic state (**Figure 7**).



**Figure 7.** Overall condition of patients with primary lung tumors in relation to length of time of taking Megamin

Observations were made on 53 patients with digestive tract carcinoma in the terminal phase of illness. The effect of Megamin in these patients was weaker, because of its slower activity in intestinal tract (**Figure 8**).



**Figure 8.** Overall condition of patients with digestive tract carcinoma in relation to length of time of taking Megamin

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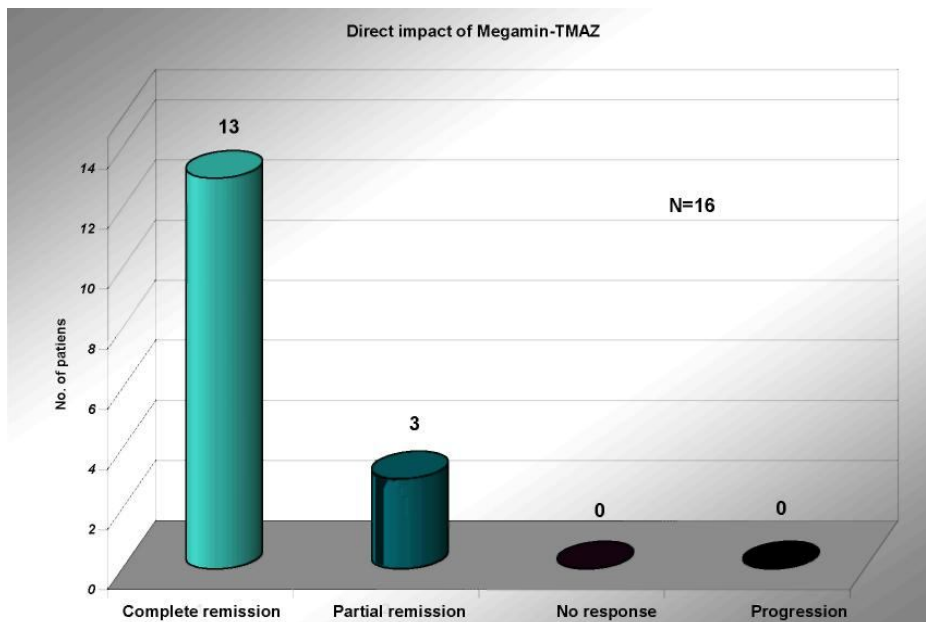
In addition, it was noted that all patients suffered chemotherapy and radiation treatments better.

c) Doctors at the Svečnjak Polyclinic in Zagreb observed the effects of Megamin in 32 patients over a period of 3 years beginning in late August 1998 until September 2001. This group of patients were divided into two subgroups:

- 16 patients who chose monotherapy with Megamin
  - 16 patients who used Megamin as a supplemental adjuvant therapy
- Both groups of patients received 16 capsules and four teaspoonfuls of Megamin powder daily. After three years of observation the following results were obtained:

- In the group receiving only Megamin therapy (4 with metastatic melanoma, 3 with liver cancer, 2 with microcellular carcinoma of the bronchus, 2 with prostate cancer, 1 with bladder cancer and 1 with hepatocellular carcinoma) –13 patients, or 81 % of the subjects showed complete remission after 3 years of exclusive Megamin treatment, while 3 patients (two with lung cancer and 1 with breast cancer) or 19 % showed partial remission and stabilization of their illness (**Figure 9**).

- In the second group, complete remission was observed in 8 patients, or 50 %, while partial remission along with stabilization of the tumor and establishment of control over the disease was observed in the remaining 8 patients or 50% (**Figure 10**)

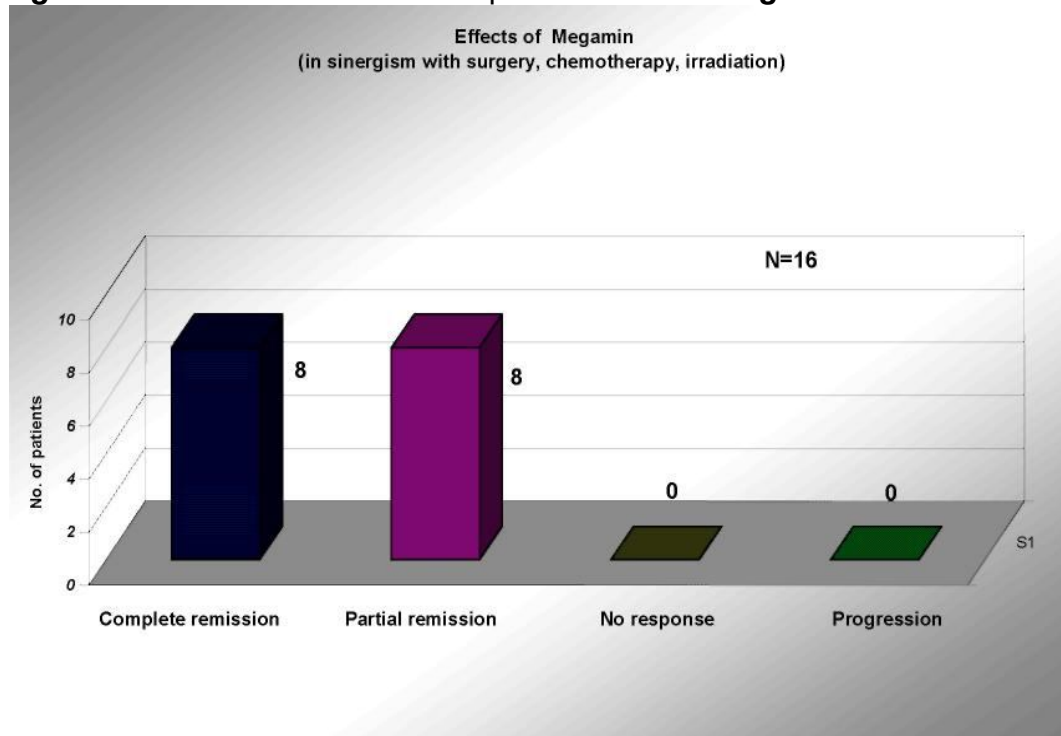


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**Figure 9.** Results of the monotherapeutic effects of *Megamin*



**Figure 10.** Results of the effect of Megamin in synergism with chemotherapy and irradiation

- Megamin treatment in patients after heart surgery - recuperation (Russian Research Centre of Surgery) (**supplement 20**)

The study included 18 male patients with arteriosclerosis and coronary heart diseases. They all were hospitalized RZCK RAMN and were being prepared for aortic-coronary/mammario-coronary by-pass implantation surgery. All the patients have had a severe myocardial heart attack over the period of the last 7 years. Results obtained after Megamin application show the positive effect on homeostasis as well as elimination of free radicals and metabolites in all the patients. That was particularly favorable to improvement of blood cells function and plasma purity, which led to improvement of blood circulation. That effect could be compared to plasmoferase effect. The positive changes in characteristics of fibrinous stopper indicate that Megamin eliminates oxidized fibrinogens.

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- Anti oxidative and hemodynamic effect of Megamin in patients with diabetes and coronary heart diseases (the Zaporzje Medical Academy) (**supplement 21**)

This study included 20 patients with diabetes and coronary heart diseases, mostly angina pectoris. Such patients have extremely high values of lipid peroxidase oxidation as a result of oxidative stress caused by the above mentioned diseases. After 4 weeks of Megamin application a decrease in levels of lipid peroxidase, a decrease in the left ventricular mouth by 6 % in diastole and 16 % in systole, an increase in MVC by 12 % and a decrease in UPOZ by 10 % were noted in all the patients. Much more significant changes occurred in functional characteristics: FE increased by 28 %,  $\Delta S$  increased by 15 % and Vcp increased by 20 %. It is important to emphasize that E/A transmitral blood level increased by 18 %. Anti oxidative effect of Megamin helped improve geometry of the left ventricle and its function in contracting and diastole activities. It was also noted that Megamin acted hypoglycemiaally in all treated patients.

- Effect of TMAZ on blood cells (**supplement 22**)

This short study ascertained TMAZ effect on stimulation of production and activity of blood cells. Testing was performed on 29 healthy and 29 postoperative persons.



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## 6.5. CLINICAL STUDIES

- Clinical testing of TMAZ in immunodeficiency (**supplement 23**)

Therapeutic use of Megamin and Lycopomin has shown that immune - modulation of B-lymphocytes, T-lymphocytes and NK-cells can be achieved in a very short period of time. Since in many diseases, particularly in diseases of immune system, specific influences on pathogenesis of disease can be exerted, application of these products is extremely valuable especially thanks to its natural structure.

That is an explanation of therapeutic effects on different diseases. Using Megamin and Lycopomin preparations based on Zeolite, the following diseases can be treated by complex immune-modulation:

Primary and secondary immunodeficiency

Auto immunologic diseases

Over sensitiveness reactions

Immunocomplex diseases

Neoplasia

Malignant diseases of immune system

Neuroimmunological and psychiatric syndromes

- Clinical testing of Megamin in psoriasis (Klinomed-Helios) (**supplement 24**)

In this clinical study 20 patients, between 25 and 77 years of age, all with advanced stage of psoriasis were tested. The testing lasted for 12 weeks and all the patients were given Megamin 3x1 capsule a day. CrP, DKS and differentiation of lymphocytes (CD3, CD4, CD8, CD16, CD56) were observed. There was noted improvement in clinical pictures, both on the skin and in blood count.

After the period of 12 weeks, 19 out of 20 patients have not shown any symptoms of disease.

After finishing the study, the patients were observed further over the period of 3 months in order to find out to what degree the patients were subjected to relapse.



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It was noticed that symptoms recurred in 8 patients, which indicates the need of post-therapeutic taking of preparation for an indefinite period of time.

• Clinical testing of Megamin in diabetes mellitus type 2 (Klinomed-Helios) (**supplement 25**)

The testing included 30 patients with diabetes mellitus type II. During the testing, the following laboratory values were observed:

C-peptides; insulin; Pro-insulin; HbA<sub>1c</sub>; cholesterol; HDL-cholesterol; LDL-cholesterol; triglycerides; sugar. After 3 months of Megamin treatment, reduction in HbA<sub>1c</sub> and triglycerides was noted in all the patients. Clinical condition of patients improved, primarily in connection with typical diabetic complications.

Laboratory Values	Diabetes Type	Amount	1. Test		2. Test		3. Test	
			MW	SD	MW	SD	MW	SD
C-Peptide	Diatic	8	3,89	2,65	4,54	2,57	5,13	1,92
	Tablet	12	3,77	1,79	3,96	2,14	5,43	2,39
	Insulin	10	2,51	1,83	3,11	2,02	3,00	1,06
	Combined	30	3,38	2,08	3,83	2,22	4,54	2,15
Insulin	Diatic	8	17,31	10,92	33,28	32,95	22,90	13,17
	Tablet	12	21,08	16,73	29,49	27,97	30,75	27,69
	Insulin	10	41,63	23,55	74,58	46,48	51,65	40,38
	Combined	30	26,92	20,53	45,53	40,84	35,62	31,33
Proinsulin	Diatic	8	39,58	23,14	32,90	21,84	34,71	25,53
	Tablet	12	24,08	19,69	25,88	20,84	23,13	20,48
	Insulin	10	22,04	14,07	18,14	14,02	14,58	8,96
	Combined	30	27,52	19,82	25,17	19,35	23,37	20,09
HbA <sub>1c</sub>	Diatic	8	6,61	0,65	6,65	0,80	6,85	0,92
	Tablet	12	7,13	1,20	7,05	1,21	7,11	0,93
	Insulin	10	6,85	0,60	6,63	0,70	6,86	0,67
	Combined	30	6,90	0,90	6,80	0,95	6,96	0,83
Cholesterol	Diatic	8	6,34	1,59	6,26	1,31	6,08	0,91
	Tablet	12	5,60	1,38	5,95	1,51	5,73	1,61
	Insulin	10	4,93	0,70	5,02	0,72	4,83	0,66
	Combined	30	5,57	1,34	5,72	1,31	5,52	1,26
HDL- Cholesterol	Diatic	8	1,33	0,32	1,46	0,32	1,33	0,32
	Table	12	1,31	0,29	1,37	0,31	1,36	0,33
	Insulin	10	1,21	0,24	1,19	0,23	1,22	0,25
	Combined	30	1,28	0,28	1,33	0,30	1,30	0,30
LDL-	Diatic	7	3,93	1,35	3,72	1,19	3,36	0,70



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Cholesterol	Tablet	11	3,59	1,16	3,73	1,18	3,47	1,23
	Insulin	9	3,11	0,69	3,10	0,69	2,94	0,69
	Combined	27	3,52	1,09	3,50	1,04	3,26	0,97
Triglyceride	Diatic	8	2,74	1,58	3,05	1,81	3,49	2,46
	Tablet	12	1,79	1,34	1,86	0,82	2,28	1,48
	Insulin	10	1,65	1,60	1,60	0,78	1,75	1,21
	Combined	30	1,99	1,51	2,09	1,26	2,42	1,80
Insulin	Diatic	8	7,32	2,18	8,44	2,39	8,61	2,22
	Tablet	12	10,16	4,64	9,91	3,45	11,25	3,97
	Insulin	10	9,13	4,78	9,50	4,53	9,59	4,19
	Combined	30	9,06	4,21	9,38	3,55	9,99	3,72



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## **7. RESEARCHES IN PROGRESS**

### **7.1 H P V**

In Croatia, preparations are underway for clinical trials on the effects of TMAZ in vaginal infections and HPV. Testing on 90 patients is being prepared under the leadership of the head of the clinic, Dr. Kuvačić.

All so far carried out studies of individual application of antiviral preparations based on TMAZ, Colostromin capsules and vaginal suppositories, have shown encouraging results in elimination of HPV-virus and decrease in CIN, and indicate positive results of further clinical investigations as well.

Colostromin capsules consist of TMAZ, powdered Colostrums and propolis. Vaginal suppository is of the same composition.

### **7.2 PSORIASIS, NEURODERMITIS**

In Germany and Switzerland, double-blind trials are underway in patients with psoriasis. Out of 300 patients, 150 ones receive local application, while 150 ones receive combined oral and local application of TMAZ.

All so far obtained anecdotal results of observing patients with the above mentioned diagnoses, as well as the first clinical observation in 20 patients, have shown 100 % response in healing, so good results of clinical investigations can be expected.

The preparations that are applied for the mentioned indications are: Megamin capsules and TMAZ, skin powder.

### **7.3. PROSTATE CANCER**

At the Swiss Aeskulap clinic in Brunnen, investigations are underway on the effects of TMAZ and Lycopenomin on prostate cancer.

Preliminary results in smaller doses show significant improvement in 8 out of 14 patients, PSA-value in these patients have been systematically decreasing and reached the value which indicates the possibility of complete remission of disease. It is important to mention that the patients who had not reacted to conservative methods of medical treatment were chosen for testing.

After consulting with the leader of research, Prof. Ben Pfeiffer, the therapeutic dose was doubled in expectation of significant improvement in condition in 3 more patients.



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## 7.4. BREAST CANCER

At the same clinic, the pilot study of TMAZ effect on 22 female patients with breast cancer was carried out. Those were the patients to whom the medical therapy could not help.

During the therapy which lasted 6 months, it was found out that disease was significantly withdrawing in at least 16 patients, and in others stabilization was noted.

It was especially interesting to observe a positive reaction of a patient in the terminal state who was taken to the clinic after she had experienced the terminal phase of disease and had been without any hope for possible remission of disease. After she was examined with PET-scan and scintigraphy, it was determined that she had 38 metastases spread all over the body, especially 2 big metastases on pericardium which generated water in the pericardium and caused suffocation attacks.

Prof. Pfeiffer recommended to that patient to take TMAZ in dose of od 4 X 3,0 dr. a day, but the patient, after she had felt some improvement of overall condition, quadrupled the dose on her own. Intensive taking of TMAZ resulted in withdrawal of the metastases on the pericardium within 4 days, significant improvement of overall condition of the patient and remission of other metastatic formations.

## 7.5. ADRENAL GLAND CANCER

The clinic pilot study of testing of TMAZ effect on hypernefrom is being carried out on 10 terminal patients in the Helios clinic in Dresden under the leadership of Dr. Brockman. The patients are given 6X4,0 gr. of TMAZ and 8 capsules of Megamin forte and Megamin plus.

Temporary results:

After 6 months of observing 2 patients died, 4 are completely stabilized, and 4 do not show any symptoms characteristic of this serious disease.



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## 8. CONCLUSION

With a series of results documenting the positive effects of tribomechanically activated Zeolite in a series of anecdotal cases involving various health problems in people, scientific research was begun in 1997 to investigate the potential effects of tribomechanically activated Zeolite – (TMAZ) on biological systems.

The scientific investigations included testing the acute, sub acute and chronic toxicity of TMAZ, effects of TMAZ on various canine tumors, TMAZ's influence on cancer (*in vivo* and *in vitro*), on autoimmune diseases, psoriasis, *diabetes mellitus*, on liver disease, the possibilities for use of Megamin in the treatment of wounds, in neurodegenerative diseases, in transitory hypogamaglobulonaemia, as well as testing its anti oxidative effects.

Results of investigations so far, as well as use in practice, indicate the necessity to continue to the research, with a multicentre approach and with various goals.

It has definitely been confirmed that TMAZ, particularly in its derivations (Megamin, Lycopomin, etc), when combined with some other effective natural active substances, is a very effective oxide-reductive and immune-modulating preparation, and probably the most powerful antioxidant in the world that is taken orally. Therefore, in this phase of the research the conclusion can already be drawn that its use as a roborant in adjuvant therapies, as well as for prophylaxis and improvement of immunity in healthy people is to be recommended.



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