

**Pilot study to verify the effects of Cicatrix<sup>®</sup> cream  
application (CATALYSIS, S. L. Madrid)  
in patients with keloid and hypertrophic scars**

**Final Report**

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**For: CATALYSIS, S. L. Madrid**

**Svidník, April 2007**

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## **Introduction**

During the period from August 1<sup>st</sup>, 2006 until April 15<sup>th</sup>, 2007 a **Pilot study to verify the effects of Cicatrix® cream application (CATALYSIS, S. L. Madrid) in patients with keloid and hypertrophic scars** was carried out at the Private Department of Dermatovenereology DOST, Svidník, Slovak Republic.

For the purposes of the study, the said preparation, namely Cicatrix® cream was selected and delivered by the company CATALYSIS, S. L. Madrid and employed in practice.

The product has undergone molecular activation.

## **Keloid and hypertrophic scars**

What often plays a decisive role during the first minutes of contact with another person is the overall appearance and the physical attributes. These attributes, unfortunately, might be affected quite negatively by scars. For the majority of population, hypertrophic and keloid scars seem to pose a long-term aesthetic and mental problem. They often limit both the professional as well as the social life of those who are affected.

The capacity of skin to repair after various types of damage induced (mechanical, chemical, thermal, by cold or frost), including post traumatic and post surgical damage is individual in every human being. The same type of trauma can have totally different healing course in two individuals. Unfortunately, not all people react adequately, showing integral healing of the traumatised skin. An unaesthetic or otherwise disturbing scar requires efficient treatment. This treatment is required by all patients, who are, however, not at all interested in the pathophysiological processes of skin healing.

The issue of skin healing as such as well as the possibilities of skin damage corrections ought to be thoroughly understood by every expert involved in scar management.

Connective tissue reactions called healing sometimes resulting in the formation of scar tissue is a very complex process. Scar tissue is rich in collagen fibres, but contains little vessels and cells. There are no hair follicles, sebaceous or perspiratory glands, as those never repair in the process of healing. In favourable conditions a smooth transparent discreet scar is formed, blending into the surrounding skin. The colour of new scars is reddish, sometimes with brownish or bluish colouring. Scars mature within the course of 8 to 18 months, their colour changing gradually, becoming whitish or adjacent-skin-like. In some cases pigments are deposited causing darker scar coloration, and sometimes the typical depigmentation known as the "halo effect" emerges around the scar.

"Per primam" healing occurs in neat post-surgery wounds. In cases of prolonged secretion phase accompanied by the formation of granulated tissue and delayed epithelisation we speak of healing „per secundam". Yet another type of healing is seen after inflammatory skin lesions (acne). These scars are known as **hypertrophic scars**, their opposite variant being atrophic scars.

**Spontaneous keloid scars** emerge after uncontrolled proliferation of collagen structures and their aetiology is unknown. **Classic hypertrophic scars** emerge after burn injuries, other scars, such as **radial scars** we observe in irradiated patients. We could continue naming the types of scars in which clinical differentiation is sometimes quite difficult (for instance hypertrophic scar versus keloid). Apart from the typical localities (shoulders, sternum, neck) **spontaneous keloid scars** may emerge on the whole body skin surface. An important role is played here by racial and genetic factors, physical influences and some serious diseases.

#### **Therapeutic possibilities:**

The most effective therapy of new hypertrophic scars and keloids includes intralesional application of corticoids, however, connected to a certain systemic effect risk for the patient. In Australia, the first positive results of silicone material employment were presented in the eighties (strips, ointments), whereby there were many extensive international studies carried out and elaborated to prove the presumed positive effects of silicone especially in patients with burn complications (8). Surgical interventions are not used frequently nowadays because of the risk of frequent relapses and neither is cryotherapy, as it may cause long-term depigmentation and its effects are insignificant and disputable.

After the initial uncritical interest in laser therapy, this option is not taken advantage of so widely nowadays, mainly due to lack of experience.

*What shall remain part of the therapy of keloid and hypertrophic scars with satisfactory effects are combined approaches using the combination of topical application of preparations containing herbal extracts such Centenella asiatica, and rehabilitation, massage, pressure and occlusive therapy procedures. Best results are obtained following topical preparation of a preparation containing (Extractum cepae, Centenella asiatica) or heparin in combination with massage, pressure and occlusive therapy procedures, rehabilitation balneotherapy and pulverisation, or a combination of a number of the named procedures.*

Lately, many expert monothematic publications have been issued and many congresses held regarding scar management, attended by experts in various fields of medicine.

There are elaborate studies in literature on scar remodelling and cosmetic management (12) at the disposal nowadays, and there are many experts in favour of using silicone sheets in various types of scars, whereby many methods to apply those sheets have been recommended already (2, 5, 9). The agents on the market include SIL-K (STM s.r.o.) and Topigel (Incom Trading s.r.o.). A new generation of topically applied preparations with very promising effects (1) includes Cica-Care (Smith+ Nephew) – an adhesive semioclusive transparent silicone gel applicable in the treatment itself, as well as in the prevention of hypertrophic scars.

Laser therapy to manage scars is still used by those advocating this type of treatment (especially in the USA) and possible combinations of techniques are being sought constantly, which would potentiate the resulting final effect. Most popular combinations include laser employment and the application of silicone sheets and polymer bondages named Silon-TSR. These materials are used as temporary skin substitutes after skin resurfacing, dermabrasion or suffered burns. The effects reported are quite manifest (13). Another representative of modern materials - Silon-SES Elastomer has been used with great effects in the management of post-burn hypertrophic scars lately. To treat atrophic scars, preparations containing collagen,

including injectable filling materials are used such as Artecoll, COLLAGENPLUS, Restylan, Matrigel, Matridex, Surgiderm, Viscontour and others.

Despite all the facts stated and the variety of methods available to treat hypertrophic and keloid scars none of them seems to be 100% efficient, as there are more significant and less manifest results, according to individual response of single patients. Certain methods are contraindicated in some patients (intralesional corticoids), others are too time or money consuming. It may happen that their final effect is minimal despite the efforts made by the therapist (1, 12, 17, and 19).

On the other hand, the lengthy therapy of hypertrophic and keloid scars poses no problem to most affected patients as they are usually very patient after having tried various methods of questionable effects, but still yearning to get results. They are usually willing to try those new methods with promising effects.

New scars react more promptly to any type of therapy, but must not be irritated by physical means, which is something all patients must be informed of. During therapy, the treated locality should be protected from extreme cold and especially from sun exposure. Intensive massage also is not recommended.

Excellent effects were observed following the application of a preparation containing the extracts of Ectractum cepae, Alantoinu and Heparin titled Contractubex<sup>®</sup> to a relatively broad range of scars. Literature states great effects following the application of this product to restore tissue functionality in hypertrophic burn scars (4), in cases of induratio penis plastica and Dupuytren's contracture (10, 16). These preparations are safe in children (4) when used to treat scars emerging after cryotherapy (7) and are extraordinarily effective in post-surgical scars (3, 6, 11, 14, 15) and spontaneous keloids (11, 18, 20). Good effects have been observed following the application silicone gel labelled Dermatix, containing a high content of Heparin, Centenella Asiatica, and Aloe Vera.

*Due to the broad variety of scars and to the number of these defects developed by the population it is always great to be able to welcome a new promising product that would*

*bring relief to the affected patients. Cicatrix® cream, Catalysis, S. L. Madrid, seems to be such a preparation; moreover, it has undergone the process of molecular activation which potentiated its actions.*

### **Product characteristics:**

Cicatrix® cream is a new product by Catalysis, S.L. Madrid, employed to treat keloid and hypertrophic scars. The active substances contained in the cream include Centella Asiatica 1.0% and Pinus Sylvestris 0.5%. The said active substances and molecular activation safeguard the efficacy of the product in adequate indications. Other components include: Abil B8839, Sk-Influx, Tego Alkanol 1618, Glycerin and others (see production standard)

### **Study objective:**

To verify the efficacy and tolerability of the preparation Cicatrix® cream, a product by Catalysis, S.L. Madrid, in patients with keloid and hypertrophic scars and to evaluate differences in tolerability and in the final effect in individual patients.

### **Study type:**

Prospective randomised controlled study of type IV; with post-registration monitoring and continuous inclusion of patients into the study according to set criteria and age.

### **Study design:**

30 patients aged from 1 to 65 years of various sex and defect extent instructed in the topical application of Cicatrix® cream, CATALYSIS, S. L. Madrid to localities with hypertrophic and keloid scars.

<b>Time schedule:</b>	June 2006 – December 2006:	patient inclusion and exclusion
	August 1 <sup>st</sup> , 2006 - March 30 <sup>th</sup> , 2007:	study performance
	April 2007:	study results assessment and processing
	May 2007:	handing over of a complete results assessment
	May - December 2007:	presentation and publication of results

## Materials and methods

The clinic carrying out the study agreed that they would elaborate the documentation, take pictures, and inform the ordering party about any conditions in connection with the performance of the study.

The clinic worked with and according to the following **basic set of documents**:

- Basic working protocol (Annex 1)
- Inclusion and exclusion criteria (Annex 2)
- Working and assessment table (Annex 3)
- Total number of patients (Annex 4)
- Patient consent form (Annex 5)

<b>Clinic:</b>	DOST Svidník
<b>Study duration:</b>	8 months, from August, 1st 2006 to March 31st, 2007
<b>*Group of patients:</b>	30 patients (9 male, 21 female)
<b>*Average age:</b>	35.55 years (24.5 years of age in women, 46.6 years in men) The youngest patient is a male aged 10 months.
<b>Diagnosis:</b>	keloid and hypertrophic scars of various extent and aetiology
<b>*Disease duration:</b>	average duration of 2 years, with the shortest period of 2 months
<b>Disease extent</b>	1 x 2cm up to 10 x 15 cm on the average, solitary as well as multiple scars
<b>Local finding assessment:</b>	performed 4 times – at the inclusion into the group of patients and after 2, 6 and 8 weeks
<b>Final assessment:</b>	upon study termination
<b>Preparation employed:</b>	Cicatrix <sup>®</sup> cream, Catalysis S.L. Madrid

**The qualitative and quantitative composition of CICATRIX<sup>®</sup> CREAM is as follows:**

### ACTIVE PRINCIPLE:

Centella Asiatica	1.0	%
Pinus Sylvestris	0.5	%

### EXCIPIENTS:

Abil B8839	7.0	%
Sk-Influx	5.0	%
Tego Alkanol 1618	3.0	%
Glycerin	3.0	%
Varonic APS	3.0	%

Tego Alkanol S 2 P	2.4	%
Estearic Acid	1.0	%
Parafin	0.8	%
Tego Alkanol S 20 P	0.6	%
Sodium Hydroxide	0.4	%
Hycare	0.2	%
Tego Carbomer	0.2	%
Parfum	0.1	%
Aqua	71.8	%

**Patient information:** provided by the therapist.

All patients have been informed about possible adverse effects

**Inclusion criteria:**

- Keloid and hypertrophic scars of various extent
- Defect duration of minimum 3 months
- Male or female sex, Caucasian
- Resistance to previous therapy
- Inpatient or outpatient status
- Age of more than 10 months
- Voluntary participation in the trial
- Written patient consent form confirmation
- One-time participation in the trial

**Exclusion criteria:**

**Specific exclusion criteria:**

- Known allergies to the tested preparation
- Disease focus infection manifestations (superinfection requiring therapy)
- Immunosuppressive therapy
- Cancer
- Malignancies
- Employment of other drug/s and /or preparation/s in therapy

**General exclusion criteria:**

- Alcohol and/or drug abuse
- Painkiller abuse
- Participation in another clinical trial within the past 30 days
- Simultaneous participation in any other clinical trial
- Other reasons excluding the patient from the trial
- Restricted ability of the patient to follow therapy instructions
- Other physical or mental disorders disturbing the trial plan
- Possible consent withdrawal, presumed patient unreliability

**Number of applications:** 2 -3 times a day until condition improvement is reached,

**Important note:** it is necessary to strictly follow the recommended massage movements and adhere to the treatment system for at least 8 weeks

\* **Application duration:** at least 120 days

**Concomitant employment of other methods:** after 4 weeks the earliest

**Other medication:** employed in emergency cases exclusively and based solely on recommendation of other medical experts

**Laboratory screening:** performed 2 times – prior to therapy commencement and after therapy termination  
(the results obtained are not subject of this study and therefore irrelevant)

**Documentation:** work protocol

**Photodocumentation:** pictures taken during regular check-ups

**Recommended daily hygiene:** non irritating preparations having no influence on study course

**Therapy effect assessment:**

(1- healing, 2 – significant improvement,  
3 – improvement, 4 – no improvement, 5 – aggravation).

**Therapy assessment made by the patients:**

(1- excellent, 2 – very good, 3 – good,  
4 – without changes, 5 – aggravation, irritation)

*Comment: The differing application periods of topical Cicatrix® cream, Catalysis S.L. Madrid were conditioned by the extent of the areas to be treated as well as the volumes of the said preparations delivered by the company.*

*Note: data marked with \* are to be found in Tables No. 1, Graphs No. 1, and 2*

*The figures in columns indicate the numbers of patients*

**Results**

**Basic data:** For gender, number of patients, age (lowest, highest), average application duration period (in days), average disease duration period (in years), average exacerbation period duration and number of relapses per year **see Table No. 1, and Graphs No. 1 and 2.**

**Specialised data:** For application discontinuation, hospitalization, and most effective preparations **see Table No.2 and Graphs No. 3, 4, and 5**

**Specific data:** For efficacy and tolerability, assessments made by the therapist and the patients, and for adverse effects **see Table No. 3, and Graphs No. 6 to 11**

**Diagnoses:** In the group of 30 patients (consisting of 9 men and 21 women), there were keloid and hypertrophic scars of various forms and extents, from small 1x1 cm scars to extensive burn scars affecting areas of 10 x 15 cm.

Their aetiology (spontaneous keloids, trauma, vaccination, surgical interventions, burns) was nor relevant for the purposes of the study.

**Previous therapy:** 50% of patients had used a number of topical preparations (Contractubex<sup>®</sup>, Dermatix<sup>®</sup>, Lioton<sup>®</sup> gel, silicone sheets), balneotherapy, laser therapy, cryotherapy, intralesional corticoids

**Positive family anamnesis:** 2 patients (6.66%) with spontaneous keloids

**Laboratory screening:** 2 patients: elevated cholesterol level  
 4 patients: liver tests results on the verge of normal ranges,  
 3 patients with glycaemia on the verge of normal range  
 2 patients: elevated CRP levels  
 3 patients: elevated FW levels

**Other medication:** roborans, vitamins, antihistaminic agents

Other medication was employed in emergency cases exclusively and based solely on recommendation of other medical experts

**Other recommended physical therapy methods:**

pulverization, massage – possibly starting at therapy commencement

**Any other methods were employed 4 weeks following therapy termination:**

Biostimulation laser II. B, microdermabrasion, intralesional corticoids, occlusion

**Local finding improvement** was observed already within the first 3 weeks in 30% of the patients and continued until the termination of the application of the tested topical preparations

**Remission** impossible to be assessed so far due to lack of time, however, none of the patients showed aggravation

**Therapy efficacy (see Table No. 3, Graphs No. 6, 8, 9, 10):**

Assessment made by the therapist: 15 (50.00%) patients very good  
 11 (37.00%) patients good  
 3 (10.00%) patients without effect  
 1 (3.3%) patient did not tolerate the therapy.

Assessment made by the patients: 13 (43.00%) patients very good  
 12 (40.00%) patients good  
 3 (10%) patients without effect  
 2 (6.70%) patients aggravation

***Therapy tolerability (see Table No. 3, Graphs No. 7, 8, 9, 10):***

Assessment made by the therapist: 15 (50.00%) patients very good  
 11 (37.00%) patients good  
 3 (10.00%) patients without effect  
 1 (3.3%) patient did not tolerate the therapy.

Assessment made by the patients: 13 (43.00%) patients very good  
 12 (40.00%) patients good  
 3 (10%) patients without effect  
 2 (6.70%) patients aggravation

***Tolerability:*** of Cicatrix<sup>®</sup> cream, Catalysis S.L. Madrid was very good and good

**Adverse effects (following the application of Cicatrix<sup>®</sup> cream, Catalysis S.L. Madrid)  
 (see Table No. 3, Graph No. 11):**

1 patient with skin burning sensation (3.33%),  
 1 patient with short term skin dryness (3.33%),  
 5 patients with skin reddening (17.00%),  
 3 patients with itching (10.00%)

None of the patients discontinued application.

***Irritative dermatitis:*** observed in 4 patients and resolving in 10 days

***Patients excluded from the group:*** 1 patient was excluded after 4 weeks

***Hospitalised patients:*** none

**Comment:**

Cicatrix® cream, Catalysis S.L. Madrid was applied in 30 patients.

The approach consisted of basic steps:

1. washing the affected skin area or scar gently, preferably with soap, liquid soap or shower gel containing 3-8% Ichthamol
2. pulverization
3. massage
4. after a month, the condition was assessed and combined therapy and further possible therapeutic approaches were considered.

All patients have been instructed in massage techniques and obtained instructions in writing. Patients were shown how to apply the preparation and instructed in pulverisation. **We consider this effect especially important, as it is not sufficient to apply the preparation superficially, as its mere application does not lead to permanent improvement.**

During previous studies (regarding the therapy of keloid and hypertrophic scars) carried out at our clinic (16, 17, 18, 19) we have proven that the suggested system of massaging movements, that we have developed and used in practice for more than 15 years fosters gradual loosening of the rigid scar fibres and causes great final effects. In combination with pulverisations using thermal water the effect is even more potentiated.

**Pulverisation** is a special way of treating damaged or disease affected skin (for example in burnt patients, patients with atopic dermatitis or psoriasis) using thermal water and fine massage. In some defects it is possible to increase the therapeutic effect by massaging the skin with special ointments and emulsions.

**Procedure:** wash the affected skin area or scar gently with soap, preferably with soap containing 3-8% Ichthamol (SANO disinfection soap or DETA Werra body wash). Dry the skin using a soft towel and spray it with thermal water (preferably with high selenium content), apply a thin layer of Cicatrix cream and massage the skin using recommended massage movements.

It is possible to repeat pulverisation while performing massage so that the skin remains moisturised. The pressure applied to skin should not be too weak or too strong, actually, the

pressure piled ought to equal the pressure of a regularly firm handshake. After the massage the focus must be wiped and a thin layer of Cicatrix ought to be applied.

All patients were instructed in the necessity to perform massage at least 2 times a day for the minimum of 1 month and checked by the therapist, who recommended further approach. All patients were instructed to contact the therapist should irritation occur!!

***Other therapeutic methods employed combined with the studied cream application:***

**Occlusion (Table No. 2):** 11 patients – 36.67% (5 men, 6 women).

Occlusion (plastic foil or inert bioocclusive material) was performed after evening treatment and left on the site for approximately 8 hours. 6 patients complained of burning sensation after 10 days. Objectively, we revealed the occurrence of erythema and the application of occlusion was therefore discontinued. In 5 (17.00%) patients the effect was very good and healing acceleration was evident as the scars were flattening. In those patients occlusion was applied until therapy termination.

**Microdermabrasion (Table No. 2):** 13 patients – 43.33% (4 men, 9 women)

Microdermabrasion of every focus was performed once a week using the grid movement system repeated three times.

***This combined therapy (massage, pulverisation, and microdermabrasion) seems to have best effects.*** We therefore recommend this combination be used at clinics equipped with a microdermabrasion device.

**Biostimulation type II.B. laser (Table No. 2):** 18 patients – 60% (6 men, 12 women). Its usage in the treatment of keloid scars has been known for years, and we applied this laser 2 times a week with a very good effect.

***We therefore presume that the combination of massaging, pulverisation and biostimulation laser accelerates healing*** and influences the final aesthetic effect.

**Intralesional corticoids (Table No. 2):** 6 patients – 20% (2 men, 4 women). Applied in those patients with unconvincing effects mainly in localities, in which the tested preparation was only applied without using massage movements or pulverisation (years, navel).

**Undesired effects:**

***Irritative dermatitis*** - occurred in 4 patients (13.33%) after 10 to 12 cream application days. It is possible those patients had not properly understood the therapy system and did not adhere to therapy instructions. The symptoms resolved after approximately 10 days following application discontinuation and two patients started applying the cream again after that. In the other two patients intralesional corticoids were applied later on.

**Bacterial infection:** Two patients reported they had been suffering from a bacterial infection in the course of therapy (which is a contraindication of Cicatrix® cream, Catalysis S.L. Madrid application), and have discontinued therapy until the symptoms of bacterial infections were treated and resolved. The observed therapy was then continued.

**Most significant effects** were observed **in patients with new scars** – in a little boy after cleft palate operation and a boy bitten by a dog.

Very good effects were observed following the application of Cicatrix® cream Catalysis S. L. Madrid in patients with atrophic scars and striae cutis distensae (also considered atrophic scars). Patients were applying Cicatrix® cream using the recommended massage system and pulverisation. 4 patients with acne scars and 5 patients with stretch marks were treated. After 6 weeks of therapy the cosmetic effects were very good (see pictures).

Cicatrix® cream was applied in 8 patients ***outside the studied group***.

Very good effect was observed in a female patient who developed granuloma after lip augmentation with filling materials. After the granuloma had been expelled scarring occurred. Following 4 weeks of Cicatrix® cream application the condition was healed totally (see pictures).

Cicatrix® cream was applied also to a patient suffering from ***discoïd lupus erytematosus for 20 years***. Within topical therapy, the patient would use corticoids, which resulted in skin atrophy. Moreover, their effect was not manifest anymore, with ulcerations emerging. Following the application of Cicatrix® cream, the local finding improved after 3 weeks, the skin was smoothened and small ulcerations and erosions healed. This patient has been using Cicatrix® cream with great effects for 3 months already (see pictures).

Cicatrix® cream Catalysis S. L. Madrid was applied also to 2 patients with superficial ***gazes***, in 2 patients with ***burns of I. and II. severity degree*** and 2 female patients with ***skin***

***irritation after depilation.*** The application of Cicatrix® cream Catalysis S. L. Madrid caused resolution of irritation, erythema and infiltrations symptoms within 6 days.

In patients with **older scars** it is necessary to **prolong the application period**, and combine it with other therapeutic approaches stated above.

The patients were satisfied with the therapy and the resulting aesthetic effects were satisfactory.

Both the therapist and the patients appreciated the texture of Cicatrix® cream.

## **Discussion**

Cicatrix® cream is a new product by Catalysis, S.L. Madrid, employed to treat keloid and hypertrophic scars. The active substances contained in the cream include Centella Asiatica 1.0% and Pinus Sylvestris 0.5%. These active substances are responsible for its efficacy under adequate indication and application conditions. The product has undergone the process of molecular activation.

**Molecular activation is** a novel unique method to improve the biological activity of all antioxidants, vitamins, trace elements and herbal extracts. Molecular activation increases the activity of the said molecules 20 – 100 times. The chemical composition remains unchanged, while their bioactivity is increased.

Spanish scientists working in Madrid laboratories have been examining the activities of antioxidants and free radicals since 1980. In every substance, more than 20 parameters and physical and biological properties are monitored, whereby specific properties are determined to balance out the negative effects of free radicals in organisms responsible for health problems.

Centenella asiatica has been used in medicine for many centuries; however, it was only in the fifties of the previous century an adequate extraction of the active components was performed successfully.

Gotu kola extract (titred extract of Centenella asiatica – TECA), Madecassoside and Asiaticoside are the most important components of the preparation, showing activity. They all have been described many a time, including their excellent effects shown to treat venous hypertension, vessel circulation, oedema or varicose veins. They also decrease the level of cholesterol and demonstrate antibacterial activity.

TECA extracts can foster collagen synthesis in arterial walls and maintain their tonus. What is really interesting is the knowledge obtained about the changes of human fibroblasts induced by the triterpenoids of *Centenella asiatica*. TECA testing on animals has proven their absolute safety. Of course the advantages of its topical application have been verified and proven by many studies and documented experiments in the field of wound healing acceleration were performed, describing the ways to promote skin healing after radiodermatitis therapy and the treatment of experimental wounds and scars. TECA animal testing has also proven analgesic effects in small animals as well as the fact that some Gotu kola components may interfere with fertility in mice.

TECA is alleged to act as an aphrodisiac – however, this has not been proven by research so far.

TECA has been tested in a row of clinical trials and the presumption has been proven that its application accelerates the healing of surgical wounds, leg ulcers of various aetiology, parasitic skin diseases, skin diseases of pemphigous group and scars. The healing itself is not accompanied by any damage or scarring.

TECA testing has also shown that the extract of *Centenella asiatica* is capable of destroying carcinogenic cell cultures; however, it will be necessary to perform many a clinical study to prove the alleged anticancerous effect.

Madecassoside shows evident and verified anti-inflammatory effect (verified by French medical studies) proven while monitoring the condition of patients with hepatic lesions. TECA application was followed by significant improvement of the condition. TECA may be applied topically or administered systemically.

*It has been clearly proven that Madecassoside and Asiaticoside accelerate and improve collagen synthesis in the process of wound healing and they also improve the quality of collagen fibres – namely their firmness, as has been proven by experimental observations of application in patients with scleroderma (where they were used as auxiliary preparations).*

**A highly positive effect was shown in wound healing acceleration.** Systemic TECA application is not recommended in children under 1 year of age, pregnant and lactating women and in persons treated with hypoglycaemic agents (described interaction).

***The employment of Madecassoside and Asiaticoside (Madecassol) is an excellent way to prevent keloid and hypertrophic scars formation. Their application is considered as***

*effective as any other treatment methods including the application of external corticoid drugs (intralesional injections) and continuous pressure bandages.*

The subject of the research is the bacteriostatic action of madecassoside. However, its action against mycobacteria has not been clearly verified yet.

TECA employment scope: Asiaticoside and Madecassoside contained in medical products show activity in wound healing, the treatment of burns and venous insufficiency. They demonstrate an anti-aging effect and counteract the changes caused by cellulite. Excellent effects have been described in patients with acne, virginal problems, and fungal infections.

Madecassoside is employed highly purified, improving significantly the repair of epidermis for example after various types of laser treatment, peeling and minor surgical interventions. It improves the quality of wrinkled skin and slows down the formation of wrinkles, shows anti-aging effect, improves the condition of post-inflammatory hyperpigmentations, cellulite, weather-induced skin irritation or small haematoma.

Exceptionally, following topical application irritative dermatitis or rash may occur, but resolve quickly.

## **Conclusion**

The application of Cicatrix<sup>®</sup> cream, Catalysis S. L. Madrid can be employed within classic conservative monotherapy or combined therapy. It is comfortable, non invasive, painless and affordable. It is well tolerated, has practically no contraindications and may be employed in children without any problems.

**The high percentage of therapy efficacy in the group of 26 patients subjected to this study amounting to 87% (very good a good efficacy) makes the studied preparation new centre of attention and opens new employment possibilities.**

*Cicatrix<sup>®</sup> cream, Catalysis S. L. Madrid has no ambition to become the universal treatment instrument in scar management. However, it represents a very elegant and highly efficient therapeutic possibility that ought to be taken advantage of by all therapists.*

In the group of patients we observed good therapeutic response in most patients. Adverse effects emerged sporadically. Only one patient discontinued application and was excluded from the studied group. The cases of irritative dermatitis that occurred in the group have been described already in literature by other authors and are generally known.

Cicatrix<sup>®</sup> cream Catalysis S. L. Madrid, in our opinion, should be applied, due to great effects obtained, in combination with other recommended methods to treat keloid and hypertrophic scars – microdermabrasion, biostimulation laser or intralesional application of corticoids. The effects of all the said methods are potentiated, healing is accelerated and cosmetic and aesthetic effects achieved are highly satisfactory. All this has great influence on the mental comfort of the patients.

**The preparation may be applied in children without any risk.** It is recommended to treat cryotherapy-induced scars , is extraordinarily effective in post-surgery scarring and spontaneous keloids and can be applied after laser resurfacing (however, only after the crusting and secernation have resolved).

We came to the conclusion that it is advisable to distribute the preparation in tubes in the future, so that the risk of contaminating the cream with dirty fingers is eliminated.

**We perceive Cicatrix<sup>®</sup> cream Catalysis S. L. Madrid as a preparation with great future employment prospect, showing activity in influencing the final condition of keloid and hypertrophic scars as well as other diagnoses based on the decision made by the therapist.**

**In order to improve its effects as much as possible it is inevitable to apply Cicatrix<sup>®</sup> cream in the recommended way using massage movements (as it accelerates the deterioration of rigid scar fibres and curbs the synthesis of capillaries) combined with pulverisation.**

**We do not recommend application to patients with proven skin allergy and to perform epicutaneous testing prior to therapy commencement.**

**We recommend an international multicentre study be carried out.**

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## **Annex I**

## **Annexes 1 -5**

## **Annex II – Tables**

## **Annex III – Graphs**

## **Annex IV – Photodocumentation**

**Annex V - CD**