Herbal preparation and its application

The invention relates to a herbal preparation with anti-inflammatory and astringent actions used in the herbal medicine to treat conditions related to the interruption of the anatomical continuity of the outer layers of the skin or deeper tissues.

Herbal preparations are widely used in herbal medicine, cosmetics and conventional medicine. Its effect is due to the presence of biological active substances, which act after application on the skin. Superficial skin inflammation are very serious problem. Untreated or inadequately treated can be a cause of the infection. The healing process is painful and often limited mobility and quality of life. An important and still current problem in medicine is the rate of healing of various wounds – both caused by mechanical factors (abrasions, lacerations, cuts) as well as thermal or chemical (burns), as well as a side effect of other diseases - such as diabetes and the related problem of diabetic foot.

All significant injuries caused vascular damage and interruption of their continuity and thus initiate molecular and cellular response leading to the activation of the hemostasis process. The healing process can not be initiate, until hemostatic mechanisms not work, which are the multifactorial and multistep process. The most important element of hemostasis is blood clotting, leading to the clot formation. The clot consists mainly of gird of the fibrin and embedded

on them platelets. The clot formation is very important process. It prevents further loss of fluids and electrolytes from the wound and reduces pollutions from the outside.

The healing process of the skin can be accelerated by the action of all kinds of chemical substances mainly of synthetic origin, which often produce additional side effects mainly affecting the weakening elasticity damaging to proteins in the skin.

The current treatment of this type disorders is generally used ointment with steroids, and with more chronic conditions strong antibiotics is used, which often cause adverse side effects.

Another way of treatment skin injuries is used eg. Calendula ointment, which contains calendula and Vaseline. When we used this ointment, however, the healing process is slow and the crust formed on the wound surface can be easily produced microorganisms. For the treatment of skin inflammation, including wound, can be also apply special herbal compositions with synergic mechanism of action.

From the international patent WO 9742963 and American patent US 5 061 491 are known herbal compositions used to treat wounds and burns. They contain in its compositions, among others, plantain, chamomile and calendula, yarrow, eucalyptus, celandine.

From the Polish patent P. 198268 is known a herbal composition for the treatment of chronic wounds, particularly used in venous ulcers and postphlebitic syndrome, which contains a mixture of herbs consisting of marigold flower, herb firefly plantain, Chamomile, Echinacea, wherein the composition comprises the active ingredients in the form of carotenoids, iridoids, aucubin, catalpol and

polyphenols, particularly flavonoid and phenolic acids in an amount resulting from the ratio contained in the composition of plants. In the world becoming clearer the trend of seeking natural substances that may replace the synthetic one.

The aim of the invention is widening of the medical preparations based on herbal extract for the treatment of conditions associated with interruption of the anatomical continuity of the outer layers of the skin or deeper tissues, which would allow the healing process and to allow to obtain the desired results even in the treatment of chronic and inflammatory complications after surgery.

Surprisingly, the herbal preparation, according to the invention, is equal pharmacological formulations with a bactericidal or bacteriostatic properties, which has exacerbated therapeutic effect leading to a rapid self-cleaning skin inflammation with interruption the anatomical continuity of the outer layers or deeper tissues and complete their healing without causing side effects.

The herbal preparation, according to the invention, contains plant extract emulsified or suspended in an organic medium is characterized in that the as active substance contains alcohol extract from *Melittis melissophyllum L.*, and other active substances such as flavonoids, polyphenols, tannins, amine compounds and bitter substances and mineral salts.

The alcoholic extract of the melittis contains a *Melittis melissophyllum* herb in an amount from 10% to 40% w/w, ethyl alcohol in an amount from 10% to 20% w/w.

The herbal preparation in the form of the ointment contains as an organic medium Vaselinum album in an amount from 40% to 70% w/w.

There is preferably, when the herbal preparation in the form of the ointment contains glycerol or propylene glycol in an amount of 2% w/w, triethylamine in an amount of 2% w/w, hydroxycellulose in an amount of 1% w/w and aqua purifficata in an amount from 30% to 35% w/w.

Another aspect of the invention is the use of the herbal preparation to treat various types of wounds and skin inflammations.

The herbal preparation, according to the invention, shows normal epithelial growth and accelerates granulation. It allows to maintain longest moisture of the wound environment, which accelerates their filling, wherein due to the long duration occurred the destruction of the connective tissue and subcutaneous tissue and growth epidermis.

The herbal preparation based on the herbal extract from melittis – *Melittis melissophyllum* L. contains active substances such as tannins, polyphenols flavonoids, amine compounds, bitter substances and mineral salts

The studies showed, primarily, large amounts of tannins which have astringent properties and the ability to create especially with collagen insoluble and irreversible connections which are not subject to putrefaction. In addition, they are active astringently for mucous membranes preventing hemorrhage from the capillary blood vessels, they also inactivate bacteria and their toxins, and they are also have anti-inflammatory properties. Otherwise, the presence of the flavonoids as a means of sealing the walls of small blood vessels have been used as anti-bleeding compounds, preventing ecchymosis and

varicose veins. Their activity is associated with inhibition of enzymes present in the vessel walls – hyaluronidase which is responsible for the degradation one of the intracellular substances and increase of permeability of the intracellular spaces. It also have been shown that they have anti-aggregation potential on platelets.

The inclusion of the Melittis melissophyllum L. to the cultivation allowed to get the standardized raw material with specified quality parameters form one side, but on the other hand they allowed to increase in the population of this plant in their natural environment, thus reducing the risk of their extinction.

The present invention will be described in examples with reference to certain preferred solution, which does not limit other solutions/embodiments according to the invention.

The herbal preparation contains the extract from the Melittis melissophyllum L. was used to treat wounds of the epidermis and deeper layers of skin, in which the inflammatory processes roll on.

Example I

The following semi-sold formulation was prepared to the study obtain by mixing together:

- 40% w/w Melittis melissophyllum L. from the whole plant,
- 20% w/w 96% ethyl alcohol,
- 40% w/w Vaselinum album (hydrocarbon medium used in lipophilic ointments).

Etched by the ethyl alcohol substance is dissolved with heating in the smooth ointment medium in order to better dispersion (a biologically

active compounds contained in the test extract). It could be mixed also in cold lipophilic medium. It is important that the substance has been dissolved in the medium at the concentration below saturation.

In the study was involved three groups of animals with open wounds:

I control group – it was not apply any treatment on the wound (even antiseptic).

II group – it was used typical antiseptic agent – chlorhexidine (according with the standard protocol of the treatment of infected wounds)

III group – it was used the preparation with Melittis melissophyllum L. extract.

The phagocytic activity of neutrophils was assessed using phagocytic index (PI) - the percentage of phagocytic containing adsorbed latex particles, and an amount of phagocytes (IF) - the average number of molecules per phagocyte.

The results of the effect of the application of alcohol extract of *Melittis melissophyllum L.* during epithelialization (epidermal) and wound healing in rats showed in Table 1.

The results of determining the level of phagocytic activity of leukocytes in healing of the wound surface after application of the alcohol extract of *Melittis melissophyllum L.* mammal showed in Table 2.

Table 1.

	Gropu		
	control	Chlorhexidine	*Melittis melissophyllum L.*
Beginning epitelialization, 24-hrs	5,0±0,4	3,9±0,4	3,5±0,2
Beginning rejection of the crust , 24-hrs	9,0±0,5	7,6±0,5	6,5±0,4
Full crust rejection, 24-hrs	11,5±0,3	10,5±0,3	7,8±0,5
Complete wound healing, 24-hrs	13,00±0,91	11,25±0,19	9,3±0,7

Table 2.

Group	Time after granulation					
	3 day		5 day		7 day	
	Phagocytic Index (PI), %	The amount of phagocytes (IF)	PI,%	IF	PI,%	IF
Control	54,60±1,12	7,0±1,2	82,00±2,28	11,0±2,5	66,20±4,16	12,5±3,0
Chlorhexidine	61,60±9,49	10,0±2,5	59,01±4,58	14,0±3,0	48,20±5,51	11,0±3,0
Melittis melissophyllum L.	82,40±1,40	16,0±3,5	89,00±0,45	22,0±2,8	41,20±3,50[a]	9,0±1,5
PI - = FI – phagocytic index – the percentage of phagocytes containing latex particles. IF - = FF, the amount of phagocytes – the average numer of particles per 1 phagocyte.						

It was found/established that extract from *Melittis melissophyllum L.* accelerates wounds healing in experimental group of animals compared to control group. The first, region crust rejection in the third

group was starting at 6-7 days, in the control groups (saline, chlorhexidine) - 9 and 7-8 days, respectively. The final crust rejection in the third group was 7-8 day, in control group – 10-11 days. Animals receiving herb extract from *Melittis melissophyllum L.* were complete epithelialization of the wound surface at 9-th day, while the control group, in which on the wound surface the saline solution or chlorhexidine was applied, the full epithelialization of wound surface was observed at 12-13-th day.

The phagocytic activity of neutrophils from the wound surface in different periods of wound healing (increase in phagocytic indecs and number of phagocytes) due to *Melittis melissophyllum L.* extract was shown in Table 2.

It was found the first time, that the *Melittis melissophyllum L.* extract has a high therapeutic activity during wound healing period in all stages of wound healing, accelerating wound repair process and cell proliferation and therefore provide complete wound healing much earlier.

In the mechanism of action *Melittis melissophyllum L.* extract are probably involved vasodilation and normalization of microcirculation disorders, improving tissue metabolism, increased phagocytosis function of neutrophils and macrophage activation, directly or indirectly affect the proliferation of fibroblasts and angiogenesis.

Example II

It was prepared the herbal preparation consisting of:

- 40% w/w alcoholic extract of *Melittis melissophyllum L.* obtained from the whole plant by etching dry rough by 96% ethyl alcohol,
- 20% w/w 96%ethyl alcohol,
- glycerol in an amount of 2%w/w,
- triethylamine in an amount of 2% w/w,
- hydroxycellulose in an amount of 1% w/w,
- aqua purifficata in an amount of 35% w/w.

Formulation above was used in the treatment of open wounds. It was used as described in example I.

It was found that the herbal preparation based on *Melittis melissophyllum L.* definitely accelerates the repair processes during wound healing. Complete wound healing was significantly earlier.

Claims

1. Use of a herbal preparation in the manufacture of a medicament for wounds healing, wherein the herbal preparation contains as an active substance alcoholic plant extract emulsified or suspended in an organic medium containing *Mellitis melissophyllum* herb in an amount from 10% to 40% w/w, and ethyl alcohol in an amount from 10% to 20% w/w.

2. Use of the herbal preparation of claim 1, wherein the organic medium contains Vaselinum album in an amount from 40% to 70% w/w.

3. Use of the herbal preparation of claim 1, wherein the organic medium contains glycerol or propylene glycol in an amount of 2% w/w, triethylamine in an amount of 2% w/w, hydroxycellulose in an amount of 1% w/w, aqua purifficata in an amount from 30 to 35 % w/w.

4. Use of the herbal preparation of any one of claims 1 to 3, wherein the wounds are caused by damage to the skin or mucous membranes.

5. Use of the herbal preparation of any one of claims 1 to 4, wherein the herbal preparation is in the form of an ointment or gel.