



Package leaflet: Information for the patient

Dermoheal Ointment

β – Sitosterol 0.25%

Read all of this leaflet carefully before you start using this product because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This product has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Dermoheal is and what it is used for

Dermoheal is of natural and herbal edible origin, It is composed of β - Sitosterol 0.25% as the main active ingredient. The base of the ointment is composed of sesame oil and beeswax. In addition, Dermoheal contains nutritional elements needed for skin cells vitality and regeneration.

Dermoheal is used in the treatment of the following wounds:

- 1- First-degree burns, where the pain relief and the fast healing are remarkable, e.g sunburn.
- 2- Second degree burns. superficial and deep. If properly applied, no skin grafting is needed and regeneration takes place from hair follicles and glands in the dermis and subcutaneous tissue.
- 3- Third degree burns, to isolate the wound, reduce pain, and expedite nonsurgical debridement of the necrotic tissue to prepare the wound for grafting.
- 4- Donor site to decrease pain, control infection, and expedite healing (average of 7 days has been reported).
- 5- Chronic wounds including bed ulcers, diabetic foot, and leg ulcers.
- 6- Post laser resurfacing, chemical peeling, and dermabrasion.
- 7- Surgical wounds including obstetrical wounds.
- 8- Wound of circumcision.
- 9- Mucous membrane wounds such as buccal ulcers.
- 10- Cracked heels and cracked nipples.

2. What you need to know before you use Dermoheal

Moist Exposed Burn Therapy (MEBT) was introduced into medical practice since two decades In China. The concept of this therapy is to expose the wound to a physiological moist environment to enhance natural healing processes, whereby keratinocytes migration, angiogenesis, and interaction with growth factors are facilitated.

Dermoheal is an ointment which has been developed to fulfill the above criteria.

Dermoheal acts by:

- 1- Providing an optimum physiological moisture necessary for regeneration and repair.
- 2- Inducing an anti-inflammatory effect reducing thereby edema and erythema.
- 3- Creating an atmosphere unfavorable for bacterial and fungal colonization.
- 4- Isolating and protecting exposed and injured nerve endings producing thereby an analgesic effect.
- 5- Providing local nutrition for wound bed cells
- 6- Liquefying the necrotic tissue.
- 7- Isolating and protecting the wound bed from environmental factors but at the same time maintaining drainage and gaseous exchange.
- 8- Reducing body fluids loss from damaged skin (burns).
- 9- Absorbing residual heat in acute burn wounds.
- 10- Expediting epithelialization with exceptionally acceptable cosmesis.

Do not use Dermoheal

If you have ever had an allergic reaction to Dermoheal or any of its ingredients. If this applies to you, ask your doctor or pharmacist for advice without using Dermoheal.

3. How to use Dermoheal

Method of Application :

1. Burns

a) First degree burns (Superficial burns)

Dermoheal should be applied as immediately as possible. A thin layer (about 1 mm thickness) should cover the burnt area. It is better to keep the wound exposed, but if there is a need, a light dressing can be used. Reapplication should be done 3 to 4 times daily if exposed or twice daily if closed.

b) Second degree burns

First Phase – liquefying period

A thin layer of Dermoheal should cover the burnt area and renewed 3

to 4 times daily. Before reapplication, the liquefied necrotic tissue and the residues of the old Dermoheal should be wiped off gently. It is better to keep the wound exposed, but if there is a need, a light dressing can be used and a relatively thicker layer (about 3 mm thickness) should be applied and renewed twice daily.

Second Phase - repair period

Dermoheal should be applied as before, but less frequently (2-3 times daily).

Third Phase· rehabilitation period

Dermoheal should be applied as before, but only once daily.

c) Third degree burns

Dermoheal should be applied as mentioned before to liquefy the necrotic tissue.

A thin layer should cover the burnt site and renewed 3 to 4 times daily.

2- Donor Site

A thin layer of Dermoheal should cover the donor site and renewed 3 to 4 times daily if exposed or twice daily if closed.

3- Leg Ulcers

A sterile gauze should be impregnated with Dermoheal and should fill the cavity of the ulcer, and renewed twice daily.

4- Surgical and Obstetrical Wounds

Dermoheal should cover the wound in a relatively thick layer (about 3 mm) under a sterile dressing and renewed twice daily.

5- Cracked Nipples

A thin tayer of Dermoheal should be applied to the nipple under a light pad, and renewed 3 - 4 times daily. Dermoheal is safe for the infant that nursing can proceed without any hazards.

4. Possible side effects

Dermoheal is of pure herbal edible origin. No side effects to the product have been reported so far, except for rare allergic reactions to sesame oil.

Reporting of side-effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this product.

5. How to store Dermoheal

- Keep it out of the sight and reach of children.

- Do not use it after the expiry date which is stated on the outer box and tube.

The expiry date refers to the last day of that month.

- Do not store above 30°C.

- Do not use it if you notice visible signs of deterioration.

Precautions for the product

Dermoheal ointment may change its physical appearance during storage, especially during hot seasons, but it does not lose its efficacy.

6. Contents of the pack and other information

What Dermoheal contains:

The active ingredient is β - Sitosterol. Each 1 g contains 2.5 mg of β - Sitosterol (0.25% w/w).

- The other ingredients are: Sesame oil, Groundnut oil, Black cumin oil and Beeswax.

What Dermoheal looks like and contents of the pack

Dermoheal is a yellow viscous ointment available in an aluminium tube of 30 grams packed in a carton box.

Marketing Authorisation Holder and Manufacturer

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