

Dermaden™

Please read the leaflet carefully before using the cream.

This leaflet contains concise information regarding the cream.

Dermaden™ is a safe, hypoallergenic cream based solely on natural substances and rated as a medical device, free of warnings. This is not a medicine. In the event that there are further questions, please refer to a pharmacist or your doctor.

1. The cream's characteristics (what is the cream intended for?):

Dermaden™ is a cream designated to assist in the treatment of wounds, including pressure sores, diabetic wounds, burns and necrosis. **Dermaden™** pertains to a group of double-layered phospholipid protein membranes containing five systems that support the treatment and healing of wounds by means of several mechanisms.

The cream assists in the treatment and healing of the wounds in several ways:

- Neutralizes and protects against bacteria.
- Maintains the wound's cleanliness as well as a moist environment.
- Promptly reduces pain.
- Instigates rapid fusion and closing of open wounds while reducing the formation of scars.
- Promotes rapid healing and protects the wound's edges.
- Removes necrotic tissue without surgical intervention.
- Reduces the wound's odor originating from bacteria.

2. What does Dermaden™ do:

The cream acts rapidly to alleviate pain, remove secretions from the wound and acts to cleanse the wound from bacteria. During the healing and secretion removal process, the wound's area is liable to become slightly swollen and reddish until all the secretions are removed from the wound. Secretion marks could appear on the gauze and they constitute a part of the natural healing process of the wound.

*** This cream is not a medication and the product is designated for assisting in the treatment of wounds (as indicated above). ***

3. Composition:

Dermaden™ contains:

Purified Water, Bees wax, Carnuaba wax, Glycerin, Sorbitol, Lauric acid, Glyceryl oleate, Myristic acid, Stearic acid, Propylene Glycol, Sodium Polyacrylate & Ethylhexyl Stearate & Trideceth-6, Potassium Hydroxide, Lysine hcl, Glycine, Histidine, Arginin, Fructose, Phenoxyethanol

4. Special warnings before using the cream:

The cream is not designated for patients with sensitivities and/or allergies to any of the cream's ingredients. If you are sensitive to any kind of food or cream, please notify the treating physician before using the cream. The cream should not be utilized for any purpose other than that for which it has been prescribed. The cream must not be mixed with other creams.

If there is no improvement in the wound's condition or if worsening has occurred within several days, please refer to the treating physician as soon as possible.

5. How to use this cream

The cream's usage on wounds is carried out simply, easily and painlessly. The cream should be applied two to three times a day as described below.

Use instructions:

For the treatment of wounds:

- Clean and rinse the wound with lukewarm water (25 - 30°C).
- Dry the wound using soft gauze or Leave the wound to air dry for approximately 10 minutes.
- Apply a thick layer of cream onto the entire surface of the wound.
- For superficial wounds, cover the entire surface of the wound, including the wounds edges. For deep wounds, fill the entire wound's depth with cream, excluding the wounds edges.
- For obtaining the maximum effect, the action should be repeated 2-3 times a day and gradually decreasing to once a day.

The wound can be covered with gauze for absorbing the Secretion which are expected in the first few days of appliance.

- For dry wounds: a transparent film (polyurethane) or paraffin gauze affixed by a non-adhesive bandage.
- For wounds with light secretions: non-woven gauze, affixed by a non-adhesive bandage or hypoallergenic adhesive tape.
- For wounds with mid-level secretions: a non-adhesive absorbent gauze, affixed by a non-adhesive bandage or hypoallergenic adhesive tape.

For the treatment of necrosis:

- Clean and rinse the wound with lukewarm water (25 - 30°C).
- Dry the wound using soft gauze or Leave the wound to air dry for approximately 10 minutes.
- Apply a thick layer of cream onto the wound, including the wounds edges.
- Repeat the action 2-3 times a day and cover it with a gauze for absorbing the secretions which are expected in the first few days for treatment.
- After the necrosis has been removed, please follow the instruction for treating wounds above.

For the treatment of burns:

- Clean and rinse the burn with lukewarm water (25 - 30°C).
- Leave the burn to air dry for several minutes.
- Apply a thick layer of cream onto the burn surface. Bandaging is not necessary, but it is possible for absorbing secretions in case they appear.
- Keep the burn area moist, there is no limit to action repetition a day.
- Continue applying the cream until full defacing of the burn and the scar.

When reapplying, remove any dressings and cleanse the area thoroughly. Reapply as stated above.

6. How to store Dermaden™

Dermaden™ should be stored in a cool, dry place out of direct sunlight (at a temperature of 3°C - 25°C), far away from any heat source.

The cream should be stored out of reach of children and infants.

Once opened it is recommended to keep Dermaden® refrigerated (3°-10°).

The cream should not be used after the expiry date printed on the package.

Different medications/creams should not be stored within the same package.

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Manufactured by:

 Pe'er Pharm Ltd., P.C. No. 511899023
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Tel No.: 03-9024055

For:

Aigis Labs LTD.

Even Gbirol 30, Tel – Aviv

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Batch number, manufacturing date and expiry date are labelled on the package.

