

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Renebo[®] (B-sitosterol 0.25%) ointment

2. Qualitative and quantitative composition

B-sitosterol 0.25% w/w

3. Pharmaceutical form

Ointment for topical administration

Renebo[®] is golden brown to brown, homogeneous smooth ointment, free from agglomeration with characteristic sesame odor and taste, intended for topical use.

4. Clinical particulars

4.1 Therapeutic indications

Renebo[®] ointment is an herbal treatment for skin revival made of natural and herbal edible origin. It is composed of B-sitosterol 0.25% as the main active ingredient. The base of the ointment is composed of sesame oil and beeswax.

Renebo[®] is used to treat:

- First-degree burns, where the pain relief and the fast healing are remarkable, e.g. sunburn.
- 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.
- Third degree burns, to isolate the wound, reduce pain and expedite nonsurgical debridement of the necrotic tissue to prepare the wound for grafting.
- Donor site, to decrease pain, control infection, and expedite healing (average of 7 days has been reported).
- Chronic wounds including bed ulcers, diabetic foot and leg ulcers.
- Post laser resurfacing, chemical peeling and dermabrasion.
- Surgical wounds including obstetrical wounds.
- Wound of circumcision.
- Mucous membrane wounds such as buccal ulcers.
- Cracked heels and cracked nipples.

4.2 Posology and method of administration

1. Burns

- First degree burns (Superficial Burns)
Renebo[®] should be applied as immediately as possible. A thin layer (about 1mm 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.

- Second degree burns

First phase-liquefying period

A thin layer of **Renebo**[®] should cover the burnt area and renewed 3 to 4 daily. Before reapplication, the liquefied necrotic tissue and the residues of the old **Renebo**[®] 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 relative thicker layer (about 3mm thickness) should be applied and renewed twice daily.

Second Phase-repair period

Renebo[®] should be applied as before, but less frequently (2-3 times daily).

Third phase-rehabilitation period

Renebo[®] should be applied as before, but only once daily.

- Third degree burns

Renebo[®] 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 **Renebo**[®] 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 **Renebo**[®] and should fill the cavity of the ulcer, and renewed twice daily.

4. Surgical and Obstetrical Wounds

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

5. Cracked Nipples

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

4.3 Contraindications

Allergic reactions may occur in people with hyper-sensitivity to sesame oil.

4.4 Special warnings and precautions for use

Renebo[®] ointment may change its physical appearance during storage especially during hot seasons, but it does not lose its efficacy.

4.5 Interaction with other medicinal products and other forms of interaction

Not available

4.6 Pregnancy and lactation

Renebo[®] ointment has a high safety profile; nevertheless medicines should generally be taken during pregnancy and breast-feeding only after having previously consulted a doctor.

4.7 Effects on ability to drive and use machines

Renebo[®] ointment is not expected to cause you to be drowsy or less alert.

4.8 Undesirable effects

No side effects have been reported so far, except for rare allergic reactions to sesame oil.

4.9 Overdose

Not available

5. Pharmacological properties

5.1 Pharmacodynamic properties

Not available

5.2 Pharmacokinetic properties

Not available

5.3 Preclinical safety data

Not available

6. Pharmaceutical particulars

6.1 List of excipients

Radix scuteleria extract, Cortex phelledondri extract, Rhizome coptidis extract, Sesame oil, Arachis oil (peanut oil), White bees wax, Butylated hydroxyanisole, Colloidal silicon dioxide.

6.2 Incompatibilities

None Known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Renebo[®] ointment is packed in internally lacquered aluminum tubes with latex end seal screw capped with white HDPE conical / piercer cap.

Internal lacquer: double coated epoxide / phenolic resin as primary packaging material and packed in cartoon box as secondary packaging material.

Pack size: 30gm

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

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8. Marketing authorisation number(s)

Registration Number:

Renebo[®] 30gm ointment:

05763/07370/REN/2020

08850/07622/VAR/2021

9. Date of first authorisation/renewal of the authorisation

Registration Date:

Renebo[®] 30gm ointment: Mar 15, 2021

10. Date of revision of the text

04/2020