

Luxamend™

Wound Cream

Rx Only

DESCRIPTION

Luxamend™ is a water-based emulsion formulated for the dressing and management of superficial wounds; minor abrasions; dermal ulcers; donor sites; 1st and 2nd degree burns, including sunburns; and radiation dermatitis. When applied properly to a wound, Luxamend provides an optimum moist environment for the healing process.

INDICATIONS AND USAGE

Luxamend is indicated for use in:

- Full Thickness Wounds, Pressure Sores, Dermal Ulcers including Lower Leg Ulcers
- Superficial Wounds
- 1st and 2nd Degree Burns, including Sunburns
- Dermal Donor and Graft Site Management
- Radiation Dermatitis
- Minor Abrasions

CONTRAINDICATIONS

Luxamend is contraindicated for use on bleeding wounds, skin rashes related to food or medicine allergies, and when an allergy to one of the ingredients is known.

WARNINGS

- In radiation therapy, Luxamend may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.

- Do not apply Luxamend to dermal grafts until after the graft has successfully taken.
- Keep out of the reach of children.

PRECAUTIONS AND OBSERVATIONS

- For the treatment of any dermal wound, consult a physician. Use Luxamend only as directed.
- Luxamend is non-toxic; it is for topical use only and should not be ingested or taken internally.
- Luxamend does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- The use of Luxamend on skin rashes due to allergies has not been studied sufficiently and therefore is not recommended.
- Following the application of Luxamend, a temporary tingling sensation may occur (10–15 minutes).
- If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of Luxamend may be continued during the anti-infective therapy.
- If condition does not improve within 10–14 days, consult a physician.
- Luxamend may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

INSTRUCTIONS FOR USE

Luxamend™ is for topical use only as directed by a healthcare professional.

Wounds, Abrasions, Full Thickness Wounds, Dermal Graft Site Management and Donor Site Management

- Wash the affected area(s) with saline, clean water or a suitable wound cleanser.
- Apply Luxamend on and around the affected area(s) in thick layers ¼ to ½ inch thick.
- If applying gauze dressing, moisten the dressing lightly before application.
- Reapply Luxamend as described above every 24 to 48 hours or as directed until the wound or lesion has healed fully.
- For donor site management, apply Luxamend after skin removal and cover with a moist dressing. Reapply as directed.
- For dermal graft site management, apply Luxamend to the graft site only after the graft has taken successfully. Luxamend can be washed away with a saline solution or clean water without causing damage to the newly formed tissues.

1st and 2nd Degree Burns, Including Sunburns

- Before application of Luxamend to burns, take precaution in removing any clothing in the affected area(s).
- Apply Luxamend as soon as possible on and around the affected area(s), in a thick ¼ to ½ inch layer until the skin no longer absorbs the product. A white waxy residue may remain. If pain from the burn persists, apply thinner layers of Luxamend until the pain has ceased.
- Continue to apply Luxamend until the affected area(s) has healed completely.
- Application of Luxamend to the affected area(s) should continue during any subsequent physical therapy treatments.

Radiation Dermatitis

- Apply a generous amount of Luxamend three times per day, seven days a week to the treated area(s), gently massaging the area(s) until Luxamend is completely absorbed.
- Luxamend may be applied as indicated by the treating physician (see WARNINGS).
- Continue to apply Luxamend as described above until the skin has fully recovered.
- Do not interrupt applications during the course of radiation therapy, even for one day.
- Do not apply Luxamend 4 hours prior to a radiation session.

INGREDIENTS

Luxamend contains purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (potassium salt), propylparaben (sodium salt) and allergen-free fragrance.

HOW SUPPLIED

Luxamend is supplied in a 114 gram tube. NDC 69489-521-14.

Store at room temperature. Avoid excessive heat.

Do not freeze.

Rx ONLY

Prescription Medical Device: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Manufactured for:



Journey Medical Corp.
Scottsdale, AZ 85258
1-877-801-1298

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Made in U.S.A.