



Controlled Release Skin Barrier Emulsion

EpiCeram[®]

Rx Only

For Topical Dermatological Use Only

Product Description

EpiCeram[®] Controlled Release Skin Barrier Emulsion is a steroid free, fragrance free ceramide dominant emulsion containing ceramide, conjugated linoleic acid (CLA), and cholesterol in an emollient base. These physiological lipids are delivered via a patented time-release system to insure a physiological level over time and maximal performance. The delivery technology is based on a unique proprietary system consisting of multi component microspheres that contain submicron spheres. These submicron spheres are infused with the physiological lipid in an active form and optimal configuration. Rubbing the emulsion onto the skin triggers this two-step delivery system. Once the microsphere is broken the submicron spheres gradually deliver the physiological lipids over time. The special microsphere structure stabilizes the lipids from premature oxidation yielding a product at its highest efficacy.

Indications for Use

EpiCeram[®] Controlled Release Skin Barrier Emulsion is to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, and radiation dermatitis. EpiCeram[®] helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Contraindications

EpiCeram[®] Controlled Release Skin Barrier Emulsion is contraindicated in persons with known hypersensitivity to any of the components of the formulation.

Warnings

EpiCeram[®] Controlled Release Skin Barrier Emulsion does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas. In radiation dermatitis and/or in conjunction with ongoing radiation therapy apply following radiation therapy. Do not apply within 4 hours prior to radiation therapy. Apply twice daily or as indicated by the radiation therapist. After application, a temporary tingling sensation may occur (10 to 15 minutes). Keep this and similar products out of the reach of children. Follow directions for use. If condition does not improve within 10 to 14 days, consult a physician.

Precautions and Observations

For the treatment of any dermal wound, consult a physician.

- Use EpiCeram[®] Controlled Release Skin Barrier Emulsion only as directed.
- EpiCeram[®] is non-toxic, however it is for external use only and should not be ingested or taken internally.
- If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of EpiCeram[®] may be continued during the anti-infective therapy.

- If the condition does not improve within 10-14 days, consult a physician.
- EpiCeram[®] does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas.
- In radiation dermatitis and/or in conjunction with ongoing radiation therapy, apply following radiation therapy.
- Do not apply within 4 hours prior to radiation therapy.
- Apply twice daily or as indicated by the radiation therapist.
- Following the application of EpiCeram[®] a temporary tingling sensation may occur (10-15 minutes).
- Keep this and other similar products out of the reach of children.

Instructions for Use

Apply in a thin layer to the affected skin areas 2 times per day (or as needed) and massage gently into the skin. If the skin is broken, cover EpiCeram[®] Controlled Release Skin Barrier Emulsion with a dressing of choice.

Ingredients

Purified Water, MultiSal[™] Neolipids *, Glycerol Stearate, Squalane, Glycerin, PEG-100 Stearate, Hydroxypropyl Bispalmitamide MEA (Ceramide), Petrolatum, Dimethicone, Phenoxyethanol, Cholesterol, Conjugated Linoleic Acid, Citric Acid, Palmitic Acid, Xanthan Gum, Potassium Hydroxide, Disodium EDTA, Sorbic Acid, Capric Acid.

* Proprietary microencapsulation system for gradual delivery of key ingredients including Ceramide, CLA, Cholesterol and Palmitic Acid (Formulated with E.Cerifera (Candelilla) wax, corn syrup solids, and modified food starch).

How Supplied

EpiCeram[®] Controlled Release Skin Barrier Emulsion is supplied as follows:
NDC 68040-752-17: 90 gram tube
NDC 68040-752-40: 225 gram airless pump

Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

EpiCeram is a registered trademark of
Primus Pharmaceuticals, Inc. Scottsdale, AZ 85253
MultiSal is a trademark of Salvona Technologies LLC.