

EpiCeram® Skin Barrier Emulsion

Rx only
For Topical Dermatological Use Only

Product Description

EpiCeram® Skin Barrier Emulsion is a steroid-free, fragrance-free, ceramide-dominant formulation.

Indications for Use

EpiCeram 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 Skin Barrier Emulsion helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Contraindications

EpiCeram Skin Barrier Emulsion is contraindicated in persons with known hypersensitivity to any of the components of the formulation.

Warnings

EpiCeram 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 physician.

Precautions and Observations

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

- Use EpiCeram Skin Barrier Emulsion only as directed
 - EpiCeram Skin Barrier Emulsion is nontoxic; 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 Skin Barrier Emulsion may be continued during the anti-infective therapy
 - If the condition does not improve within 10 to 14 days, consult a physician
 - EpiCeram 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
 - Following the application of EpiCeram Skin Barrier Emulsion a temporary tingling sensation may occur (10 to 15 minutes)
 - Keep this and other similar products out of the reach of children
-

Instructions for Use

Apply 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 Skin Barrier Emulsion, with a dressing of choice.

Ingredients

Capric Acid, Cholesterol, Citric Acid, Conjugated Linoleic Acid, Dimethicone, Disodium EDTA, E. Cerifera (Candelilla) Wax, Food Starch Modified Corn Syrup Solids, Glycerin, Glyceryl Stearate, Hydroxypropyl Bispalmitamide MEA (Ceramide), Palmitic Acid, PEG-100 Stearate, Petrolatum, Phenoxyethanol, Potassium Hydroxide, Purified Water, Sorbic Acid, Squalane, Xanthan Gum.

How Supplied

EpiCeram Skin Barrier Emulsion is available in a 90-gram tube. NDC 67857-800-90.
Store at 15°C to 30°C (59°F to 86°F). Do not freeze.

Marketed by
Promius™ Pharma, LLC
Bridgewater, NJ 08807
U.S. Patent No. 5,643,899

EPICERAM is a registered trademark of Ceragenix Pharmaceuticals, Inc.

Rx only – Prescription Medical Device; Federal Law restricts this device to sale by or on the order of a physician.