Privacy Called Top Personal Health Record Priority

BY MARY ELLEN SCHNEIDER

New York Bureau

Privacy should be the top priority when developing certification criteria for personal health records, a task force created by the Certification Commission for Healthcare Information Technology has recommended.

Adequate security and interoperability also must be included in certification efforts, according to the task force.

The Certification Commission for Healthcare Information Technology (CCHIT) will use these recommendations as it prepares to begin certifying personal health records (PHRs) in 2009.

The task force recommended that the voluntary certification process should apply to any products or services that collect, receive, store, or use health information provided by consumers. Certification should also apply to products or services that transmit or disclose to a third party any

personal health information. This would allow the CCHIT to offer certification to a range of products and applications, from those that offer a PHR application and connectivity as an accessory to an electronic health record (EHR), to stand-alone PHRs.

CCHIT hopes that, just as it did in the EHR field, certification will create a floor of functionality, security, and interoperability, said Dr. Paul Tang, cochair of the PHR Advisory Task Force and vice president and chief medical information officer for the

Palo Alto (Calif.) Medical Foundation.

The task force called for requirements to maintain privacy in monitoring and enforcement, and for consumer protection that would allow patients to remove their data if certification is revoked. The group also recommended that standards-based criteria be developed that would require PHRs to send and receive data from as many potential data sources as possible.

If done right, certification would have significant benefits for both physicians and patients, Dr. Tang said. A PHR could provide physicians with better access to secure, authenticated data that could help them make decisions, while patients would have more control over their own care, he said.

In July, the task force made its recommendations and handed over responsibility for PHR certification to a CCHIT work group. That work group will develop the actual certification criteria that will be used to test PHR products starting next July, according to Dr. Jody Pettit, strategic leader for CCHIT's PHR work group.

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 Barrier Emulsion only as directed
- EpiCeram Skin Barrier Emulsion 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 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

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