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Lactic Acid Cream: Package Insert / Prescribing Info

Package insert / product label Generic name: lactic acid Dosage form: cream

Drug class: Miscellaneous topical agents

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10% LACTIC ACID CREME

Relief of Dry, Scaly, Itching Skin

FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC USE.

Rx Only

Lactic Acid has been reported as an effective naturally occurring humectant in the skin. It has beneficial effects on dry skin and in severe discomfort of hyperkeratotic conditions. Vitamin E has been used as an aid to control dry or chapped skin, and for the relief of and discomfort from minor skin disorders such as burns, sunburn and irritated skin. It has antioxidant properties thus protecting the skin.

Inactive Ingredients:

Isopropyl Palmitate, Cetyl Alcohol, Glyceryl Stearate and PEG 100 Stearate, PEG 40 Stearate, Caprylic / Capric Triglyceride, Lecithin, Dimethicone, Vitamin E 3500 IU/oz, Glycerine, Methyl Paraben, Propyl Paraben, Purified Water, Disodium EDTA, Imidurea, Sodium Benzoate.

Indications and Usage for Lactic Acid Cream

For the treatment of dry, scaly skin (xerosis), ichthyosis vulgaris. Moisturizes and softens skin. For the temporary relief of itching associated with these conditions.

Warnings

Sun exposure (natural or artificial sunlight) to area of skin treated with Lactic Acid Creme should be minimized or avoided.

Precautions

FOR EXTERNAL USE ONLY. PATIENT SHOULD BE ADVISED TO KEEP THIS PRODUCT OUT OF THE REACH OF

CHILDREN. Avoid contact with eyes, lips or mucous membranes. Not for use in patients known to be sensitive to any ingredients in this product. A mild, stinging, burning or peeling may occur on sensitive, inflamed or irritated skin areas. If irritation or sensitivity occurs, patient should discontinue use and notify their PODIATRIST, DERMATOLOGIST or PHYSICIAN for appropriate therapy. Caution is advised when used on the face due to the potential for irritation.

The potential for post-inflammatory hypo- or hyperpigmentation has not been studied. Lactic Acid Creme should be given to a pregnant woman only if clearly needed, and caution should be exercised when Lactic Acid Creme is administered to a nursing mother. Safety and effectiveness in pediatric patients have not been established.

Lactic Acid Cream Dosage and Administration

Apply thoroughly twice a day onto the affected areas or as directed by your PODIATRIST, DERMATOLOGIST or PHYSICIAN.

Dispense in accordance with applicable state law. This product has not been approved by the FDA, is not listed in the Orange Book, and has not been approved or rated for therapeutic equivalence with any other product.

How is Lactic Acid Cream supplied

River's Edge Lactic Acid Creme is available in a 4 oz. (113.4g) plastic jar, NDC 68032-126-04 or an 8 oz. (226.8g) plastic tube, NDC 68032-126-08.

Store at controlled room temperature 15° - 30°C (59° - 86°F).

Rx Only.

Rev. 06/06

Packaging:

NDC 68032-126-08

10% LACTIC ACID CREME

Relief of Dry, Scaly, Itching Skin For Topical USE Only. Not for Ophthalmic USE. Rx Only

NET WT. 8 OZ. (226.8g)

RIVER'S EDGE ₩₩

PRECAUTIONS

Do not use in or near eyes, lips and mucous membranes.

- Stop use and ask PODIATRIST, DERMATOLOGIST or PHYSICIAN if irritation or sensitivity occurs.
 Do not use on face due to potential irritation.
 A mild stinging, burning or peeling may occur on sensitive, inflamed or irritated skin areas. The potential for post-inflammatory hypo- or hyper-pigmentation has not been studied.
- Should be given to a pregnant woman only if clearly needed and caution should be exercised when administered to a nursing mother.
 Safety and effectiveness in pediatric patients has not been established.

Keep out of reach of children.

DIRECTIONS

Apply thoroughly twice a day onto affected areas.

OTHER INFORMATION

Store at controlled room temperature 15°-30°C (59°-86°F).
 See package insert for additional information.
 Dispense in accordance with applicable state law. This product has not been approved by the FDA, is not listed in the Orange Book, and has not been approved or rated for therapeutic equivalence with any other product.

Manufactured for: River's Edge Pharmaceuticals, LLC. Suwanee, GA 30024.

LACTIC ACID

lactic acid cream

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:68032-126

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT) LACTIC ACID 100 mg in 1 g

Inactive Ingredients

Ingredient Name Strength

ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)

CETYL ALCOHOL (UNII: 936JST6JCN)

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)

POLYOXYL 100 STEARATE (UNII: YD01N1999R)

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

DIMETHICONE (UNII: 92RU3N3Y1O)

GLYCERIN (UNII: PDC6A3C0OX)

METHYLPARABEN (UNII: A2I8C7HI9T)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

EDETATE DISODIUM (UNII: 7FLD91C86K)

WATER (UNII: 059QF0KO0R)

IMIDUREA (UNII: M629807ATL)

SODIUM BENZOATE (UNII: OJ245FE5EU)

ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)

Packaging

Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:68032-126-04 113.4 g in 1 JAR

2 NDC:68032-126-08 226.8 g in 1 TUBE

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

unapproved drug other 06/01/2006 11/30/2011

Frequently asked questions

· What are the symptoms of lactic acidosis caused by metformin?

More about lactic acid topical

- Check interactions
- Compare alternatives
- Reviews (2)
- Drug class: miscellaneous topical agents

Professional resources

• Lactic Acid Lotion prescribing information

Related treatment guides

- Pityriasis rubra pilaris
- Dry Skin

Medical Disclaimer

DRUG STATUS

Availability

Rx and/or OTC

CSA Schedule*

N/A Not a controlled drug

User Reviews & Ratings

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Access drug & treatment information, identify pills, check interactions and set up personal medication records.





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