Rx only

LAC-HYDRIN 12%* (ammonium lactate cream) Cream

For Dermatologic use only. Not for ophthalmic, oral or intravaginal use.

DESCRIPTION: *LAC-HYDRIN is a formulation of 12% lactic acid neutralized with ammonium hydroxide, as ammonium lactate with a pH of 4.4 - 5.4. LAC-HYDRIN Cream also contains water, light mineral oil, glyceryl stearate, polyoxyl 100 stearate, propylene glycol, polyoxyl 40 stearate, glycerin, cetyl alcohol, magnesium aluminum silicate, laureth-4, methyl and propylparabens, and methylcellulose. Lactic acid is a racemic mixture of 2-hydroxypropanoic acid and has the following structural formula:

CLINICAL PHARMACOLOGY: Lactic acid is an alpha-hydroxy acid. It is a normal constituent of tissues and blood. The alpha-hydroxy acids (and their salts) are felt to act as humectants when applied to the skin. This property may influence hydration of the stratum corneum. In addition, lactic acid, when applied to the skin, may act to decrease corneocyte cohesion. The mechanism(s) by which this is accomplished is not yet known.

An *in vitro* study of percutaneous absorption of Lac-Hydrin Cream using human cadaver skin indicates that approximately 6.1% of the material was absorbed after 68 hours.

Indications and Usage: LAC-HYDRIN Cream is indicated for the treatment of ichthyosis vulgaris and xerosis.

CONTRAINDICATIONS: None known.

WARNING:
Use of this product should be discontinued if hypersensitivity to any of the ingredients is noted. Sun exposure to areas of the skin treated with Lac-Hydrin Cream should be minimized or avoided (See Precautions section).

PRECAUTIONS:
General:
For external use only. Stinging or burning may occur when applied to skin with fissures, erosions, or that is otherwise abraded (for example, after shaving the legs). Caution is advised when used on the face because of the potential for irritation. The potential for post-inflammatory hypo- or hyperpigmentation has not been studied.

Information for patients:
Patients using LAC-HYDRIN Cream should receive the following information and instructions:

1. This medication is to be used as directed by the physician, and should not be used for any disorder other than for which it was prescribed. It is for external use only. Avoid contact with eyes, lips, or mucous membranes.

2. Patients should minimize or avoid use of this product on areas of the skin that may be exposed to natural or artificial sunlight, including the face. If sun exposure is unavoidable, clothing should be worn to protect the skin.

3. This medication may cause stinging or burning when applied to skin with fissures, erosions, or abrasions (for example, after shaving the legs).

4. If the skin condition worsens with treatment, the medication should be promptly discontinued.

Carcinogenesis, Mutagenesis, Impairment of Fertility: The topical treatment of CD-1 mice with 12%, 21% or 30% ammonium lactate formulations for two-years did not produce a significant increase in dermal or systemic tumors in the absence of increased exposure to ultraviolet radiation. The maximum systemic exposure of the mice in this study was 0.7 times the maximum possible systemic exposure in humans. However, a long-term photocarcinogenicity study in hairless albino mice suggested that topically applied 12% ammonium lactate cream enhanced the rate of ultraviolet light-induced skin tumor formation.

The mutagenic potential of ammonium lactate cream was evaluated in the Ames assay and in the mouse *in vivo* micronucleus assay, both of which were negative.

In dermal Segment I and III studies with ammonium lactate cream there were no effects observed in fertility or pre- or post-natal development parameters in rats at dose levels of 300 mg/kg/day (1800 mg/m^2/day), approximately 0.4 times the human topical dose.

Pregnancy: Teratogenic effects: Pregnancy Category B. Animal reproduction studies have been performed in rats and rabbits at doses up to 0.7 and 1.5 times the human dose, respectively (600 mg/kg/day, corresponding to 3600 mg/m^2/day in the rat and 7200 mg/m^2/day in the rabbit) and have revealed no evidence of impaired fertility or harm to the fetus due to ammonium lactate cream. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, LAC-HYDRIN Cream should be used during pregnancy only if clearly needed.

Nursing mothers:
Although lactic acid is a normal constituent of blood and tissues, it is not known to what extent this drug affects normal lactic acid levels in human milk. Because many drugs are

excreted in human milk, caution should be exercised when LAC-HYDRIN is administered to a nursing woman.

Pediatric use: The safety and effectiveness of Lac-Hydrin Cream have been established in pediatric patients as young as 2 years old.

ADVERSE REACTIONS:
In controlled clinical trials of patients with ichthyosis vulgaris, the most frequent adverse reactions in patients treated with Lac-Hydrin Cream were rash (including erythema and irritation) and burning/stinging. Each was reported in approximately 10 - 15% of patients. In addition, itching was reported in approximately 5% of patients.

In controlled clinical trials of patients with xerosis, the most frequent adverse reactions in patients treated with Lac-Hydrin Cream were transient burning, in about 3% of patients, stinging, dry skin and rash, each reported in approximately 2% of patients.

DOSAGE AND ADMINISTRATION: Apply to the affected areas and rub in thoroughly. Use twice daily or as directed by a physician.

HOW SUPPLIED: LAC-HYDRIN Cream is available in cartons of 280 g (2 -140 g plastic tubes) and 385 g plastic bottle. Store at controlled room temperature, 15° to 30°C (59° to 86°F).

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