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Lac-Hydrin Lotion

Generic Name: ammonium lactate
Dosage Form: lotion

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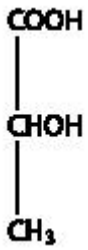
Lac-Hydrin Lotion Description

*Lac-Hydrin specially formulates 12% lactic acid, neutralized with ammonium hydroxide, as ammonium lactate to provide a lotion pH of 4.5-5.5. Lac-Hydrin (ammonium lactate) Lotion, 12% also contains cetyl alcohol, fragrance, glycerin, glyceryl stearate, laureth-4, light mineral oil, magnesium aluminum silicate, methylcellulose, methyl- and propylparabens, PEG-100 stearate, polyoxyl 40 stearate, propylene glycol and water. Lactic acid is a racemic mixture of 2-hydroxypropanoic acid and has the following structural formula:



Lac-Hydrin Lotion - 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 Lotion using human cadaver skin indicates that approximately 5.8% of the material was absorbed after 68 hours.

Indications and Usage for Lac-Hydrin Lotion

Lac-Hydrin is indicated for the treatment of dry, scaly skin (xerosis) and ichthyosis vulgaris and for temporary relief of itching associated with these conditions.

Contraindications

Lac-Hydrin Lotion is contraindicated in those patients with a history of hypersensitivity to any of the label ingredients.

Warnings

Sun exposure to areas of the skin treated with Lac-Hydrin (ammonium lactate) Lotion, 12% should be minimized or avoided (see **PRECAUTIONS**). The use of Lac-Hydrin Lotion should be

discontinued if hypersensitivity is observed.

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 (ammonium lactate) Lotion, 12% 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 transient 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 formulations enhanced the rate of ultraviolet light-induced skin tumor formation.

The mutagenic potential of ammonium lactate formulations 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 formulations 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 formulations. 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 Lotion 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

Safety and effectiveness of Lac-Hydrin have been demonstrated in infants and children. No unusual toxic effects were reported.

Geriatric Use

Clinical studies of Lac-Hydrin (ammonium lactate) Lotion, 12% did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious.

Adverse Reactions

The most frequent adverse experiences in patients with xerosis are transient stinging (1 in 30 patients), burning (1 in 30 patients), erythema (1 in 50 patients) and peeling (1 in 60 patients). Other adverse reactions which occur less frequently are irritation, eczema, petechiae, dryness and hyperpigmentation.

Due to the more severe initial skin conditions associated with ichthyosis, there was a higher incidence of transient stinging, burning and erythema (each occurring in 1 in 10 patients).

Overdosage

The oral administration of Lac-Hydrin to rats and mice showed this drug to be practically non-toxic (LD_{50} >15 mL/kg).

Lac-Hydrin Lotion Dosage and Administration

Shake well. Apply to the affected areas and rub in thoroughly. Use twice daily or as directed by a physician.

How is Lac-Hydrin Lotion Supplied

Lac-Hydrin® (ammonium lactate) Lotion, 12% is available in a 225g (NDC 10631-098-08) plastic bottle and a 400g (NDC 10631-098-14) plastic bottle.

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

RANBAXY

Jacksonville, FL 32257 USA

Revised July 2009

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

225 g extended label – front cover

225 g extended label – back cover

400 g extended label – front cover

400 g extended label – back cover

LAC-HYDRIN
ammonium lactate lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:10631-098
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMMONIUM LACTATE (LACTIC ACID)	AMMONIUM LACTATE	120 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL	
GLYCERIN	
LAURETH-4	
LIGHT MINERAL OIL	
MAGNESIUM ALUMINUM SILICATE	
METHYLCELLULOSE (100 CPS)	
METHYLPARABEN	
PROPYLPARABEN	

POLYOXYL 40 STEARATE	
PROPYLENE GLYCOL	
WATER	

Packaging		
#	**Item Code**	**Package Description**
1	NDC:10631-098-08	225 g in 1 BOTTLE, PLASTIC
2	NDC:10631-098-14	400 g in 1 BOTTLE, PLASTIC

Marketing Information

Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA019155	08/15/2008	

Labeler - Ranbaxy Laboratories Inc. (169932519)

Registrant - Ranbaxy Laboratories Inc. (169932519)

Establishment

Name	**Address**	**ID/FEI**	**Operations**
Contract Pharmaceuticals limited		248761249	manufacture

Ranbaxy Laboratories Inc.