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Lac-Hydrin

Generic Name: ammonium lactate
Dosage Form: cream

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Lac-Hydrin 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® 12% (ammonium lactate) Cream also contains cetyl alcohol, glycerin, glyceryl stearate, laureth-4, light mineral oil, magnesium aluminum silicate, methylcellulose, methyl and propyl parabens, 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 - 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 for Lac-Hydrin

Lac-Hydrin Cream is indicated for the treatment of ichthyosis vulgaris and xerosis.

Contraindications

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

Warning

Sun exposure to areas of the skin treated with Lac-Hydrin Cream should be minimized or avoided (see **PRECAUTIONS** section).The use of Lac-Hydrin Cream should be discontinued if

any 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 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 isunavoidable, 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.

Geriatric Use

Clinical studies of Lac-Hydrin® (ammonium lactate) Cream, 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

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.

Lac-Hydrin Dosage and Administration

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

How is Lac-Hydrin Supplied

Lac-Hydrin® 12%* (ammonium lactate) Cream is available in cartons of 280 g (two 140 g plastic tubes) (NDC # 10631-099-28) and 385 g plastic bottle (NDC # 10631-099-38). 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.

140 gram tube

280 gram carton

385 gram Bottle ECL (front)

385 gram Bottle ECL (back)

LAC HYDRIN CREAM
ammonium lactate cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:10631-099
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	
LIGHT MINERAL OIL	
MAGNESIUM ALUMINUM SILICATE	
METHYLPARABEN	
PROPYLPARABEN	
POLYOXYL 40 STEARATE	
WATER	
LAURETH-4	

Packaging		
#	**Item Code**	**Package Description**
1	NDC:10631-099-28	140 g in 1 TUBE

2	NDC:10631-099-38	385 g in 1 BOTTLE, PLASTIC

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA020508	03/16/2009	

Labeler - Ranbaxy Laboratories Inc. (169932519)

Registrant - Ranbaxy Laboratories Inc. (169932519)

Establishment			
Name	**Address**	**ID/FEI**	**Operations**
Contract Pharmaceuticals Limited		248761249	manufacture

Ranbaxy Laboratories Inc.