AMMONIUM LACTATE - ammonium lactate lotion
Nnodum Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Ammonium Lactate Lotion

NDC # 63044-484-09

For Dermatologic use only.

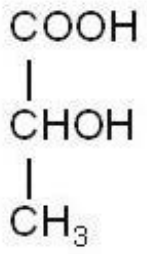
Not for Ophthalmic, Oral or Intravaginal use.

DESCRIPTION

Ammonium Lactate Lotion, 12% is a formulation of 12% lactic acid neutralized with ammonium hydroxide, as ammonium lactate with a pH of 4.4-5.4.

Ingredients: Ammonium Lactate Lotion, 12% also contains cetyl alcohol, glycerin, glyceryl stearate, light mineral oil, magnesium aluminum silicate, methyl and propyl parabens, Carbomer 940, PEG-100 stearate, polysorbate 85, triethanolamine, propylene glycol, Petrolatum and Sodium PCA, stearic acid and water.

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) may 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 Ammonium Lactate Lotion using human cadaver skin indicates that approximately 5.8% of the material was absorbed after 68 hours.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Ammonium Lactate Lotion 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 Ammonium lactate Lotion, 12% should be minimized or avoided (see **PRECAUTIONS**). The use of Ammonium Lactate Lotion 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 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/m2/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/m2/day in the rat and 7200 mg/m2/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,

Ammonium Lactate 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 Ammonium Lactate is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Ammonium Lactate have been demonstrated in infants and children. No unusual toxic effects were reported.

Geriatric Use

Clinical studies of 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 xeroxis 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 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 Ammonium Lactate to rats and mice showed this drug to be practically non-toxic (LD50 > 15 mL/kg).

DOSAGE AND ADMINISTRATION

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

HOW SUPPLIED

Ammonium lactate Lotion, 12% is available in a 225g (NDC # 63044-484-09) plastic bottle.

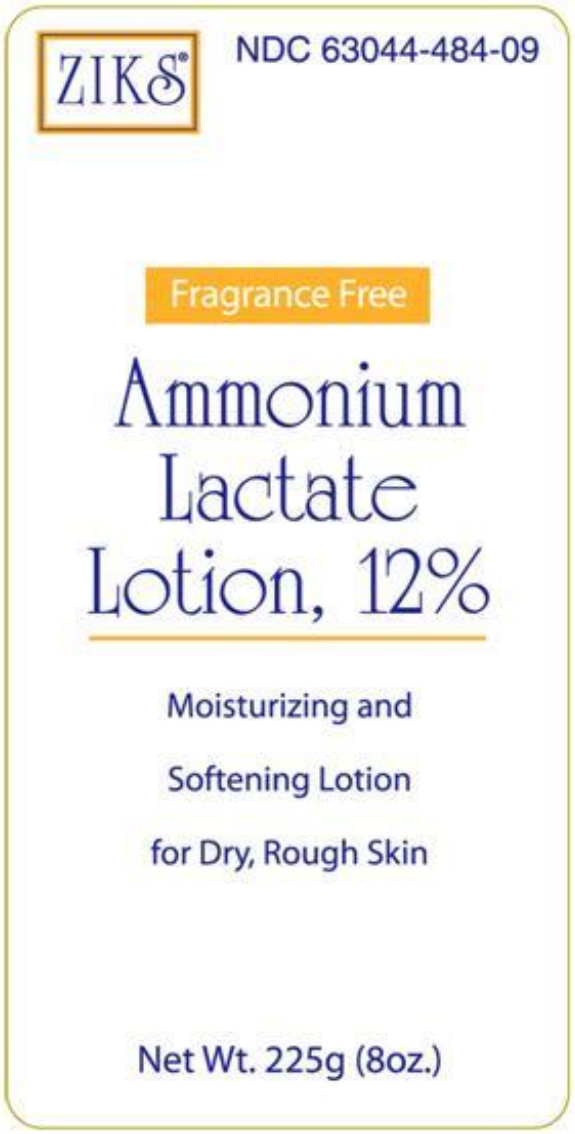
Store at controlled room temperature 15° C - 30° C (59° F - 86° F).

Manufactured for:
Nnodum Pharmaceuticals
Cincinnati, Ohio 45229
By: EMS Contract Manufacturing

Revised January 2008

Ammonium lactate Lotion

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



AMMONIUM LACTATE

ammonium lactate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63044-484
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMMONIUM LACTATE (UNII: 67M901L9NQ) (LACTIC ACID - UNII:33X04XA5AT)	AMMONIUM LACTATE	17 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE OXIDE (UNII: Y4Y7NYD4BK)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63044-484-09	225 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/30/2007	

Labeler - Nnodum Pharmaceuticals (960457273)

Establishment

Name	Address	ID/FEI	Business Operations
Alliance Packaging Group		031754588	MANUFACTURE

Revised: 12/2009 Nnodum Pharmaceuticals