

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 75-570

APPROVED LABELING

NDC 45802-419-54



Ammonium Lactate Lotion, 12%*

R only

CONTAINS: *Ammonium lactate equivalent to 12% lactic acid, light mineral oil, glyceryl stearate, propylene glycol, polyoxy 40 stearate, glycerin, magnesium aluminum silicate, laureth-4, cetyl alcohol, methyl and propyl parabens (preservatives) and water.

For external use only. Usual Dosage: See package insert for dosage information. Store at controlled room temperature 15°-30°C (59°-86° F). Lot number and expiration date on bottle.

NET WT. 225g

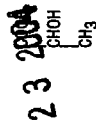
Mfg. by:
Clay-Park Labs, Inc.
Bronx, NY 10457

UPC
0-81642-41954

R only

For topical use only. Not for ophthalmic use.

Description: This product, specially formulated, 12% lactic acid neutralized with ammonium hydroxide, as ammonium lactate to provide a lotion pH of 4.5-5.5. It also contains light mineral oil, glyceryl stearate, PEG-100 stearate, propylene glycol, polyoxy 40 stearate, glycerin, magnesium aluminum silicate, laureth-4, cetyl alcohol, methyl and propyl parabens, methylcellulose, fragrance and water. Lactic acid is a racemic mixture of 2-hydroxypropanoic acid and has the following structural formula:



Clinical Pharmacology - It is generally accepted that the water content of the stratum corneum is a controlling factor in determining its flexibility. When the water content of the skin contains more than 10% water it remains soft and pliable; however, when the water content drops below 10% the stratum corneum becomes less flexible and rough, and may exhibit scaling and cracking and the underlying skin may become irritated.^{1,2}

Symptomatic relief of dry skin is provided by skin protectants containing hygroscopic substances (humectants) which increase skin moisture. Lactic acid, an α-hydroxy acid, is reported to be one of the most effective, naturally occurring humectants in the skin.³ The α-hydroxy acids (and their salts), in addition to having beneficial effects on dry skin, have also been shown to reduce excessive epidermal keratinization in patients with hyperkeratotic conditions (e.g., ichthyosis⁴).

Pharmacokinetics - The mechanism of action of topically applied neutralized lactic acid is not yet known.

Indications and Usage - Ammonium lactate lotion, 12% is indicated for the treatment of dry, scaly skin (xerosis) and ichthyosis vulgaris and for temporary relief of itching associated with these conditions.

Contraindications - Known hypersensitivity to any of the label ingredients.

Precautions - General: For external use only. Avoid contact with eyes, lips or mucous membranes. Caution is advised when used on the face of fair-skinned individuals since irritation may occur on mild, transient stinging may occur on application to abraded or inflamed areas or in individuals with sensitive skin.

Carcinogenesis, Mutagenesis, Impairment of Fertility - Ammonium lactate was non-mutagenic in the Ames/Salmonella/Microsome Plate Assay. Reproductive studies in rats given lactic acid orally showed no effect on the sex ratio of the offspring.⁵

Pregnancy, Teratogenic effects: Pregnancy Category C - Animal reproduction studies have not been conducted with ammonium lactate. It is also not known whether ammonium lactate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ammonium lactate should be given to a pregnant woman 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.

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, peeling, 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 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 - 225g plastic bottle and 400g plastic bottle.

APPROVED
23 2004

For external use only.

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

Lot number and expiration date on bottle.

NET WT. 225g

Mfg. by:
Clay-Park Labs, Inc.
Bronx, NY 10457

PMS 320, BLACK

NDC 45802-419-26



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R only

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For external use only.
Usual Dosage: See package insert for dosage information.
Store at controlled room temperature 15°-30°C (59°-86° F).
Lot number and expiration date on bottle.

NET WT. 400g

Mfg. by:
Clay-Park Labs, Inc.
Bronx, NY 10457

UPC
0-81642-41926

PULL HERE TO OPEN
PRESS TO RESEAL

APPROVED
JUN 23 2004

R only
For topical use only. Not for ophthalmic use.

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References: -

- Blank H: Further observation on factors which influence the water content of the stratum corneum. *J Invest Dermatol* 1953.
- Blank H: Factors which influence the water content of the stratum corneum. *J Invest Dermatol* 18: 433-440, 1952.
- Middleton JB: Sodium lactate as moisturizer. *Cosmetics and Toiletries* 98: 85-86, 1978.
- VanScott EJ and Yu FJ: Modulations of keratinization with α -hydroxy acids and related compounds. In: *Recent Advances in Dermatology*, E. Comar and N. Zales (eds) Spectrum Publications, Inc. NY, 211-217, 1977.
- D'Amour FE: Effects of feeding Sodium bicarbonate or lactic acid upon the sex ratio in rats. *Science* 79: 61-62, 1934.

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