**AMMONIUM LACTATE- ammonium lactate cream**
**Sun Pharmaceutical Industries, Inc.**

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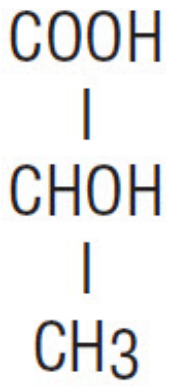
**Ammonium Lactate Cream 12%***

**Rx only.**

**For Dermatological Use only.**
**Not for Ophthalmic, Oral or Intravaginal Use.**

## DESCRIPTION

* Ammonium Lactate Cream, 12% specially formulates 12% lactic acid, as ammonium lactate to provide a cream pH of 4.5 to 5.5. Ammonium Lactate Cream, 12% also contains cetyl alcohol, glycerin, glyceryl monostearate, laureth-4, light mineral oil, magnesium aluminum silicate, methylcellulose, methylparaben, propylparaben, polyoxyethylene-100 stearate, polyoxyl 40 stearate, propylene glycol, purified water and for pH adjustment: lactic acid. 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 ammonium lactate cream using human cadaver skin indicates that approximately 6.1% of the material was absorbed after 68 hours.

## INDICATIONS AND USAGE

Ammonium Lactate Cream, 12% is indicated for the treatment of ichthyosis vulgaris and xerosis.

## CONTRAINDICATIONS

Ammonium Lactate Cream, 12% 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 Cream, 12% should be minimized or avoided (see **PRECAUTIONS**section). The use of Ammonium Lactate Cream, 12% 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 Cream, 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 the 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 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

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, Ammonium Lactate Cream, 12% 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 Cream, 12% is administered to a nursing woman.

### Pediatric Use

The safety and effectiveness of Ammonium Lactate Cream, 12% have been established in pediatric patients as young as 2 years old.

### Geriatric Use

Clinical studies of 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 Ammonium Lactate Cream, 12% were rash (including erythema and irritation) and burning/stinging. Each was reported in approximately 10 to 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 Ammonium Lactate Cream, 12% 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

Ammonium Lactate Cream, 12% is available as follows:
1-140 gram laminate tube NDC 51672-1301-2
2-140 gram laminate tubes NDC 51672-1301-4
385 gram plastic bottle NDC 51672-1301-0

**Store at 20° to 25°C (68° to 77°F)**[see USP Controlled Room Temperature].

Mfd. by:
Taro Pharmaceuticals Inc.
Brampton, Ontario
Canada L6T 1C1

Dist. by:
**Taro Pharmaceuticals**
**U.S.A., Inc.**
Hawthorne, NY 10532

Revised: October 2023

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**PRINCIPAL DISPLAY PANEL - 385 g Bottle Label**

NDC 51672-1301-4

Ammonium
Lactate
Cream 12%*


# AMMONIUM LACTATE

ammonium lactate cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:51672-1301 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMMONIUM LACTATE** (UNII: 67M901L9NQ) (LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT) | LACTIC ACID, UNSPECIFIED FORM | 120 mg in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **LAURETH-4** (UNII: 6HQ855798J) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **PEG-100 STEARATE** (UNII: YD01N1999R) | |
| **POLYOXYL 40 STEARATE** (UNII: 13A4J4NH9I) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:51672-1301-4 | 2 in 1 CARTON | 04/10/2003 | |
| **1** | | 140 g in 1 TUBE; Type 0: Not a Combination Product | | |
| **2** | NDC:51672-1301-0 | 385 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/10/2003 | |
| **3** | NDC:51672-1301-2 | 1 in 1 CARTON | 07/01/2024 | |
| **3** | | 140 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA075883 | 04/10/2003 | |

## Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Sun Pharma Canada Inc. | | 243339023 | manufacture(51672-1301) |

Revised: 7/2025

Sun Pharmaceutical Industries, Inc.