

4" x 5.5"

## KERALAC® Cream

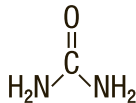
(urea 47%)

### Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

**DESCRIPTION:** Each gram contains 470 mg of urea in a vehicle consisting of: camphor, disodium EDTA, eucalyptus oil, hydroxyethyl cellulose, menthol, purified water, SD alcohol 40B 200 proof, and titanium dioxide.

Urea is a diamide of carbonic acid with the following chemical structure:



**CLINICAL PHARMACOLOGY:** Urea gently dissolves the intercellular matrix which results in loosening the horny layer of skin and shedding scaly skin at regular intervals, thereby softening hyperkeratotic areas of the skin.

**Pharmacokinetics:** The mechanism of action of topically applied urea is not yet known.

**INDICATIONS:** This product is a keratolytic emollient useful for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

**CONTRAINDICATIONS:** This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

**WARNING: KEEP OUT OF REACH OF CHILDREN.**

**PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**General:** This product is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed. If redness or irritation occurs, discontinue use and consult a physician.

**Information for Patients:** Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area

being treated or elsewhere. Avoid contact with eyes, lips and mucous membranes.

**Carcinogenesis, Mutagenesis and Impairment of Fertility:** Long-term animal studies for carcinogenic potential have not been performed on this product to date. Studies on reproduction and fertility also have not been performed.

**Pregnancy: Category C.** Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

**ADVERSE REACTIONS:** Transient stinging, burning, itching or irritation may occur and normally disappear upon discontinuing the use of this product.

**DOSAGE AND ADMINISTRATION:** Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed.

**STORAGE:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

**NOTICE:** Protect from freezing and excessive heat. Keep bottle tightly closed.

**HOW SUPPLIED:**  
5 oz. (142 g) bottles, NDC 57883-401-05

**To report** a serious adverse event or obtain product information, call 1-855-899-4237.

Distributed by:

Artesa Labs

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