

# SCALY SKIN CAN BE ROUGH

Urea loosens the cutaneous horny layer of skin and results in shedding scaly skin regularly.

- Offers relief from dry skin with 47% urea
- Steriod free
- Useful for treatment of xerosis, ichthyosis, skin cracks, fissures, eczema and psoriasis

Name \_\_\_\_\_ Date \_\_\_\_\_  
Address \_\_\_\_\_  
Rx  
**Keralac Cream**  
47% urea  
Disp: Apply 2 times daily  
5 oz. bottle  
Sig: DAW\*†  
REFILL 1 2 3 4 5 \_\_\_\_\_ M.D.  
☐ DISPENSE AS WRITTEN

Treat your  
patients with

**Keralac®**  
(Urea 47%) Cream  
Rx Only

\*Use language required by state: D.A.W. (dispense as written),  
B.M.N. (brand medically necessary), or D.N.S. (do not substitute).

†To be used for illustrative purposes only. Individual dose will vary by patient.

Visit [keralac-info.com](http://keralac-info.com) for more information.

**INDICATIONS:** KERALAC® Cream (urea 47%) is indicated for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

## Important Safety Information

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

**WARNINGS: KEEP OUT OF THE REACH OF CHILDREN.**

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

- This product is to be used as directed by a physician and should not be used to treat conditions other than that for which it was prescribed.
- If redness or swelling develop, the patient should discontinue use and contact a physician.

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

Please see reverse for full Prescribing Information.





Treat your patients with

# Keralac®

(Urea 47%) Cream

Rx Only

Clear Value Card Available

PATIENTS PAY NO  
MORE THAN **\$20**

Available for up to 12 benefits.  
Subject to eligibility. Restrictions apply.

**INDICATIONS:** KERALAC® Cream (urea 47%) is indicated for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratosis and calluses.

## KERALAC® Cream

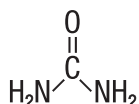
(urea 47%)

### 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, alcohol SDA 40, eucalyptus oil, hydroxyethylcellulose, menthol, water 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 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.

**WARNINGS: 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

**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.

Manufactured for:  
MISSION PHARMACAL COMPANY  
San Antonio, TX 78230 1355

R0715

**BR**AVA  
PHARMA SALES