

How to properly use

Rx ONLY
KeralacTM
LOTION (35% Urea)

In a vehicle containing Vitamin E, Lactic Acid and Zinc

**Gentle keratolytic for mild to moderate
dry skin and nail conditions**

Easy steps to gently thin and soften thick, rough or dry skin seen, to various degrees, in psoriasis, xerosis, ichthyosis, keratosis, keratoderma, dermatitis, pruritus, eczema and calluses.

Directions:

1. Apply **Keralac**TM (**35% Urea**) **LOTION** to affected skin tissue twice per day, or as directed by a physician.
2. Rub in until completely absorbed.

Also available as:

Rx ONLY
KeralacTM
CREAM (50% Urea)
In a vehicle containing Vitamin E, Lactic Acid and Zinc

Rx ONLY
KeralacTM
NAIL GEL (50% Urea)
In a vehicle containing Lactic Acid and Zinc

Rx ONLY TM
Keralac
LOTION (35% Urea)
In a vehicle containing Vitamin E, Lactic Acid and Zinc

For external use only. Not for ophthalmic use.

DESCRIPTION: Keralac™ (35% Urea) LOTION is a keratolytic emollient, which is a gentle, yet potent, tissue softener for skin. Each gram of **Keralac™ (35% Urea) LOTION** contains 35% Urea, Caprylic/Capric Triglyceride, Carbomer, Cetyl Alcohol, Cholesterol, Edetate Disodium, Glycosphingolipids, Hydrogenated Polydecene, Hydroxyethylcellulose, Lactic Acid, Linoleic Acid, Phospholipids, Polysorbate 60, PPG-5 Laureth-5, Purified Water, Sodium Polyacrylate, Sorbitan Stearate, Trolamine, Vitamin E, Xanthan Gum and Zinc Pyrithione.

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.

PHARMACOKINETICS: The mechanism of action of topically applied Urea is not yet known.

INDICATIONS AND USES: For debridement and promotion of normal healing of hyperkeratotic surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris or eschar. Urea is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, corns and calluses.

CONTRAINDICATIONS: Known hypersensitivity to any of the listed ingredients.

WARNINGS: For external use only. Avoid contact with eyes, lips or mucous membranes.

PRECAUTIONS: This medication 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.

PREGNANCY: Pregnancy Category B. Animal reproduction studies have revealed no evidence of harm to the fetus, however, there are no adequate

and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, **Keralac™ (35% Urea) LOTION** should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS: It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when **Keralac™ (35% Urea) LOTION** is administered to a nursing woman.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

ADVERSE REACTIONS: Transient stinging, burning, itching or irritation may occur and normally disappear on discontinuing the medication.

DOSAGE AND ADMINISTRATION: Apply **Keralac™ (35% Urea) LOTION** to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed.

HOW SUPPLIED:
Keralac™ (35% Urea) LOTION
7 oz (207 mL) bottle, NDC 10337-663-49
11 oz (325 mL) bottle, NDC 10337-663-11

Also available:
Keralac™ (50% Urea) CREAM
142 g (5 oz) tube, NDC 10337-658-05
255 g (9 oz) tube, NDC 10337-658-09

Keralac™ (50% Urea) NAIL GEL
18 mL (0.6 oz) bottle, NDC 10337-659-15

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

Protect from freezing.

Manufactured for: **DERMarts®** DIVISION

DOAK DERMATOLOGICS
A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

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Patent Pending