

How to properly use

Rx ONLY
KeralacTM
NAIL GEL (50% Urea)

In a vehicle containing Lactic Acid and Zinc

**Potent keratolytic for
nail and skin conditions**

Easy steps to gently thin and soften diseased, devitalized and ingrown nails, as well as thick, rough or dry skin seen in corns and calluses.

For nail tissue:

1. Apply **Keralac**[®] (50% Urea) **NAIL GEL** to diseased or damaged nail tissue twice per day, or as directed by a physician.
2. Let dry uncovered or apply and cover with adhesive bandage or gauze secured with adhesive tape.

For skin tissue:

Apply **Keralac**[®] **NAIL GEL** to the affected area(s) twice per day, or as directed by a physician.

Also available as:

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

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

For external use only. Not for ophthalmic use.

DESCRIPTION: Keralac™ (50% Urea) NAIL GEL is a keratolytic emollient, which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of **Keralac™ (50% Urea) NAIL GEL** contains 50% Urea, Edetate Disodium, Hydroxyethylcellulose, Lactic Acid, PEG-6, Propylene Glycol, Purified Water, Trolamine, 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. Urea also hydrates and gently dissolves the intercellular matrix of the nail plate, which can result in the softening and eventual debridement of the nail plate.

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, as well as damaged, devitalized and ingrown nails.

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 reproduc-

tion 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™ (50% Urea) NAIL GEL** 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™ (50% Urea) NAIL GEL** 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™ (50% Urea) NAIL GEL** to diseased or damaged nail tissue twice per day, or as directed by a physician. Apply to affected skin twice per day, or as directed by a physician.

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

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

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

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