

## How to properly use

# *Rx ONLY* **Keralac**<sup>TM</sup> **CREAM (50% Urea) Doak** In a vehicle containing Vitamin E, Lactic Acid and Zinc

Easy steps to gently thin and soften thick, rough or dry skin seen, to various degrees, in psoriasis, xerosis, ichthyosis, keratosis pilaris, keratosis palmaris, keratoderma, dermatitis, pruritus, eczema and calluses, as well as damaged, diseased or devitalized and ingrown nails.

### For skin:

1. Apply **Keralac**<sup>TM</sup> **CREAM 50%** to affected skin twice per day, or as directed by a physician.
2. Rub in until completely absorbed.

### For nail(s):

1. Apply **Keralac**<sup>TM</sup> **CREAM 50%** to affected nail(s) 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.

Rx ONLY  
**Keralac**™  
**CREAM (50% Urea) Doak**  
In a vehicle containing Vitamin E, Lactic Acid and Zinc

For external use only. Not for ophthalmic use.

**DESCRIPTION:** **Keralac™ CREAM 50%** is a keratolytic emollient, which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of **Keralac™ CREAM 50%** contains 50% urea and the following inactive ingredients: carbomer, disodium EDTA, glycerin, hydroxyethylcellulose, lactic acid, polysorbate 60, propylene glycol, purified water, sorbitan stearate, sorbitol, titanium dioxide, 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. 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 pilaris, keratosis palmaris, 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 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 reproduction studies are not always predictive of human response, **Keralac™ CREAM 50%** 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™ CREAM 50%** 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™ CREAM 50%** to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail(s) twice per day, or as directed by a physician. Let dry uncovered or apply and cover with adhesive bandage or gauze secured with adhesive tape.

**HOW SUPPLIED:** **Keralac™ CREAM 50%** is supplied as:

142 g (5 oz) tube, NDC 10337-658-05  
255 g (9 oz) tube, NDC 10337-658-09

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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