

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

For external use only. Not for ophthalmic use.

DESCRIPTION: KeralacTM OINTMENT (50% Urea) is a keratolytic emollient, which is a gentle, yet potent, tissue softener for skin. Each gram of KeralacTM OINTMENT contains 50% Urea, Purified Water, Edetate Disodium, Propylene Glycol, Hydroxyethylcellulose, Xanthan Gum, Carbomer, Polysorbate 60, Glycerin, PEG-6, Caprylic/capric Triglyceride, Linoleic Acid, Sorbitan Stearate, Cetyl Alcohol, Vitamin-E, Triethanolamine, Lactic Acid 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.

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, KeralacTM OINTMENT 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 KeralacTM OINTMENT 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 KeralacTM OINTMENT to affected skin twice per day, or as directed by a physician.

HOW SUPPLIED:

KeralacTM OINTMENT
45 g (1.5 oz) tube, NDC 10337-647-45

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

Protect from freezing.

DERMarts[®] DIVISION
Manufactured for:
DOAK DERMATOLOGICS
A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

383 Route 46 West • Fairfield, NJ 07004-2402 USA
1-800-405-DOAK • www.doakderm.com

Patent Pending

IL237
Iss. 07/05

