

How to properly use

Rx Only

KEROLTM

Emulsion (50% Urea)

In a zinc undecylenate & lactic acid vehicle

Easy steps to treat dry skin conditions including psoriasis, xerosis, ichthyosis, keratosis pilaris, keratosis palmaris, keratoderma, dermatitis, pruritus, eczema, corns and calluses.

For skin:

1. Apply **KEROLTM Emulsion** to affected skin twice per day, or as directed by a physician.
2. Rub in until completely absorbed (for best results apply to moistened skin).

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KEROLTM
Emulsion (50% Urea)
In a zinc undecylenate & lactic acid vehicle

For external use only. Not for ophthalmic use.

DESCRIPTION: Each gram of **Kerol**TM **Emulsion** contains 50% urea in a formulation consisting of: caprylic/capric triglyceride, cetyl alcohol, disodium EDTA, glycerin, hydroxyethylcellulose, lactic acid, linoleic acid, PEG-6, polysorbate 60, propylene glycol, sorbitan stearate, titanium dioxide, triethanolamine, purified water, vitamin E, xanthan gum and zinc undecylenate.

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 pilaris, keratosis palmaris, 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 reproduction studies are not always predictive of human response, **Kerol**TM **Emulsion** should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS: It is not known whether or not this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **Kerol**TM **Emulsion** 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 **Kerol**TM **Emulsion** to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed.

HOW SUPPLIED: **Kerol**TM **Emulsion** is supplied as: 10 oz tube, NDC 10337-646-10.

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