

Keratol 40™

40% Urea – Cream, Lotion or Gel



Gentle, yet potent,
tissue softener
for skin or nails.

Rx Only

For topical use only.
Not for ophthalmic use.

| NDC# (51991) - | BRECKENRIDGE PRODUCT | SIZE |
|----------------|----------------------|--------------------|
| 268-41 | Keratol 40™ Cream | 28.4 g (1 oz.) |
| 268-19 | Keratol 40™ Cream | 85.2 g (3 oz.) |
| 268-37 | Keratol 40™ Cream | 198.6 g (7 oz.) |
| 269-15 | Keratol 40™ Gel | 15 mL (1/2 oz.) |
| 270-18 | Keratol 40™ Lotion | 237 mL (8 fl. oz.) |

For more information on our products, contact your
wholesaler or distributor or visit us at www.bpirx.com.



**Breckenridge
Pharmaceutical, Inc.**
"Your ValuBrand™ Company"
Boca Raton, FL 33487

Phone (800) 367-3395
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Please see full prescribing information on back.

Keratol 40™

Cream, Lotion or Gel

(40% Urea)

Rx Only

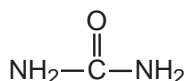
For external use only. Not for ophthalmic use.

DESCRIPTION:

Keratol 40™ is a Keratolytic, emollient which is a gentle, yet potent, tissue softener for nails and/or skin.

Each gram of Keratol 40™ Cream and Keratol 40™ Lotion contains: 40% Urea. Other ingredients: Carbomer 940, Cetearyl Alcohol (and) Ceteareth 20, Cetyl Alcohol, Mineral Oil, Polyethylene Glycol 300, Petrolatum, Purified Water, and Trolamine.

Each gram of Keratol 40™ Gel contains: 40% Urea. Other ingredients: Edetate Disodium, Glycerin, Hydroxyethyl Cellulose, PEG-6 Caprylic/Capric Glycerides, and Purified Water. 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 prurient 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, ingrown, and devitalized 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 C. Animal reproduction studies have not been conducted with Keratol 40™. It also is not known whether Keratol 40™ can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Keratol 40™ 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 Keratol 40™ 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 Keratol 40™ to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail tissue twice per day, or as directed by a physician. Store up to 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP controlled room temperature. Protect from freezing.

HOW SUPPLIED:

Keratol 40™ Cream (40%):
28.4 g (1 oz.) tube, NDC 51991-268-41
85.2 g (3 oz.) tube, NDC 51991-268-19
198.6 g (7 oz.) tube, NDC 51991-268-37

Keratol 40™ Lotion (40%):
8 fl.oz. (237mL) Bottle NDC 51991-270-18

Keratol 40™ Gel (40%):
15 mL (1/2 oz.) Bottle NDC 51991-269-15

All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

Manufactured by:
DSC Laboratories Muskegon, MI 49442 Rev 5/04

Distributed by:
Breckenridge Pharmaceutical, Inc. Boca Raton, FL 33487
Rev 3/05