

Rx Only

45% Urea Lotion

In a vehicle containing Menthol, Camphor and Eucalyptus Oil

For external use only. Not for ophthalmic use.

DESCRIPTION: 45% Urea Lotion is a keratolytic emollient, which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of 45% Urea Lotion contains 45% Urea in a formulation consisting of Camphor, Disodium EDTA, Alcohol SDA 40, Eucalyptus Oil, Hydroxyethylcellulose, Menthol, Water and Titanium Dioxide.

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, 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, 45% Urea Lotion 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 45% Urea Lotion 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 45% Urea Lotion to affected skin twice per day, or as directed by a physician.

HOW SUPPLIED:

45% Urea Lotion is supplied as a 16 oz bottle, NDC 61269-182-16

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

Protect from freezing.

Manufactured for:
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