Urea Cream, 40% Urea Lotion, 40% Urea Gel, 40%
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION
Urea, 40% is a keratolytic emollient which is gentle, yet potent, tissue softener for nails and/or skin. Each gram of Urea Cream, 40% and Urea Lotion, 40% contains 40% urea, carbomer 940, cetyl alcohol, glyceryl monostearate, mineral oil, propylene glycol, purified water, trolamine, white petrolatum, and xanthan gum. Each gram of Urea Gel, 40% contains 40% urea, edetate disodium dihydrate, glycerin, hydroxethylcellulose, PEG-6 caprylic/capric glyceride, purified water, and xanthan gum. Urea is a diamide of carbonic acid with the following chemical structure:

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\begin{align*}
&\text{NH}_2 \\
&\text{C} = \text{O} \\
&\text{NH}_2
\end{align*}
\]

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 urea 40%. It also is not known whether urea 40% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Urea 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 Urea 40% is administered to a nursing woman.

ADVERSE REACTIONS
Transient stinging, burning, itching or irritation may occur and normally disappear on discontinuing the medication.

DOSAGE AND ADMINISTRATION
Apply Urea 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.

HOW SUPPLIED
Urea Cream, 40% is available as follows:
28.35 g tube (NDC 45802-170-03)
85 g tube (NDC 45802-170-53)
198.6 g tube (NDC 45802-170-77)

Urea Lotion, 40% is available as follows:
8 FL OZ (236.6 mL) bottle (NDC 45802-176-55)

Urea Gel, 40% is available as follows:
0.5 FL OZ (15 mL) bottle (NDC 45802-171-56)

STORAGE
Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

MANUFACTURED BY
PERRIGO
BRONX, NY 10457

DISTRIBUTED BY
ALLEGAN, MI 49010

Rev 09/09