UREA 41%- urea cream
PureTek Corporation

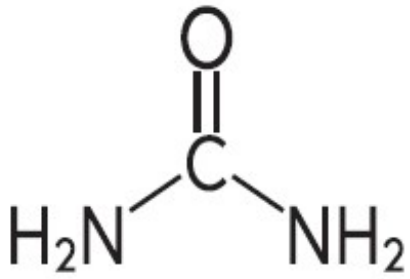
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Urea 41% Cream Rx Only

DESCRIPTION

Urea 41% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram contains 410 mg of urea in a vehicle consisting of: Aqua (Purified Water), Ceteareth-6, Ceteareth-25, Cetyl Alcohol, Methylparaben, Paraffin, Propylene Glycol, Stearyl Alcohol, Xanthan Gum.

Urea is a diamide of carbonic acid with the following chemical structure:



CLINICAL PHARMACOLOGY

Urea gently dissolves the intracellular matrix which results in loosening of the horny layer of the skin and shedding of scaly skin at regular intervals, thereby softening hyperkeratotic areas of the skin.

Pharmacokinetics

The mechanism of action of topically applied urea is not yet known.

INDICATIONS & USAGE

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 eshar. 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, as well as damaged, ingrown and devitalized nails.

CONTRAINDICATIONS

This product is contraindicated in persons with known or suspected hypersensitivity to

any of the ingredients of the product.

WARNINGS

FOREXTERNALUSEONLY.NOTFOR OPHTHALMIC USE. KEEP OUT OF REACH OF CHILDREN.

Avoid contact with eyes, lips and mucous membranes.

General

This product 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 and consult a physician.

Information for Patients

Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. Avoid contact with eyes, lips and mucous membranes.

Carcinogenesis, Mutagenesis and Impairment of Fertility:

Long-term animal studies for carcinogenic
potential have not been performed on this product to date.
Studies on reproduction and fertility also have not been performed.

Pregnancy:

Category C. Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

ADVERSE REACTIONS:

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

DOSAGE AND ADMINISTRATION

Apply Urea 41% to affected skin twice per day, or as directed by your physician. Rub in until completely absorbed.

Apply to diseased or damaged nail(s) twice per day, or as directed by a physician.

HOW SUPPLIED

Urea 41% Cream 8 oz. (227 g): NDC 59088-489-16

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat. Keep container tightly closed.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Urea 41% Cream™

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**

UREA 41%

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-489
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	410 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**

CETEARETH-25 (UNII: 8FA93U5T67)	
CETEARETH-6 (UNII: 2RJS3559D3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-489-16	227 g in 1 BOTTLE; Type 0: Not a Combination Product	06/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/07/2022	

Labeler - PureTek Corporation (785961046)

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