UREA - urea lotion
AKRON PHARMA INC

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 Lotion 40%

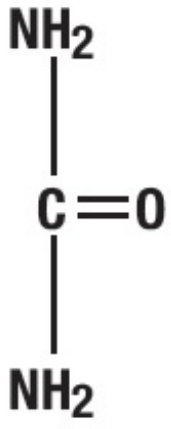
Rx Only

For external use only. Not for ophthalmic use.

Description

Urea 40% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of Urea 40% contains 40% urea as an active ingredient, and the following inactive ingredients: Purified Water, Propylene Glycol, Glyceryl Monostearate, Mineral Oil, Cetyl Alcohol, Phosphomer X-Polymer, Trolamine 99% , White Petrolatum, 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 and 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 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, as well as damaged, ingrown and devitalized nails.

Contraindications

Known hypersensitivity to any of the listed ingredients.

Warnings

For topical 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 and consult a physician.

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, 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 excreted in human milk. Because many drugs are excreted 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 upon discontinuing the medication.

Dosage and Administration

Apply Urea 40% 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 Lotion 40% 8 oz. (226.8g): NDC 71399-8455-8

Store at room temperature 15°C - 30°C (59°F-86°F). Protect from freezing. Keep bottle tightly

closed.

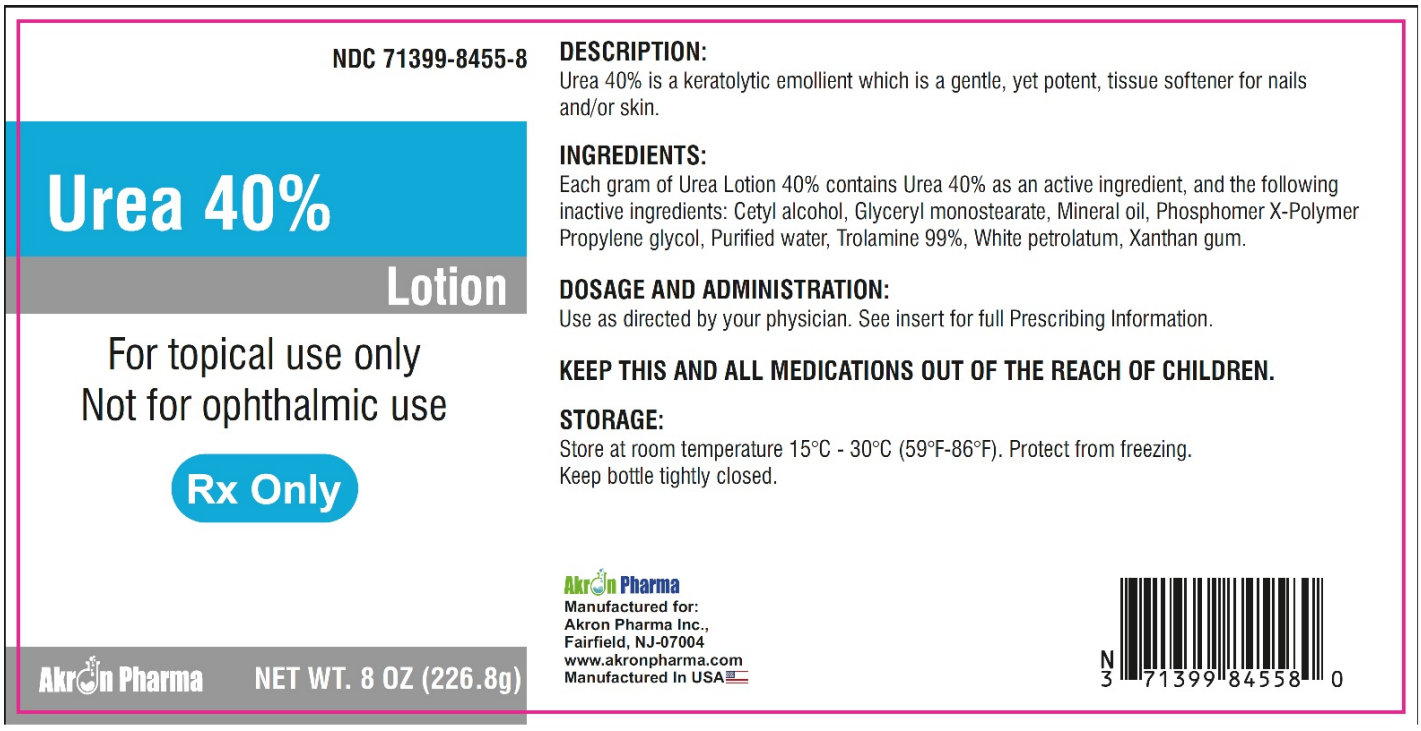
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

All prescription substitutions using this product shall be made subject to state and federal statutes
as applicable. NOTE: this is not an Orange Book product and has not been subjected to FDA
therapeutic equivalency or other equivalency testing. No representation is made as to generic
status or bioequivalency. Each person recommending a prescription substitution using this product
shall make such recommendations based on each such person's professional opinion and
knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical
formulation information provided herein.

QUESTIONS :

Please Call 1(877) 225-6999

Manufactured for:
Akron Pharma, Inc, Fairfield, NJ 07004
Manufactured in U.S.A



UREA
urea lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71399-8455
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	40 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE (UNII: 59RU860S8D)	
TROLAMINE (UNII: 9O3K93S3TK)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8455-8	227 g in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/01/2021	

Labeler - AKRON PHARMA INC (067878881)

Revised: 3/2023 AKRON PHARMA INC