UREA 40%- urea cream
Patrin 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 40% Topical Cream

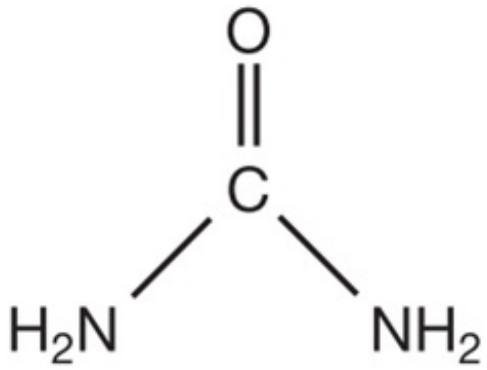
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION

Each gram contains 400 mg of urea in a vehicle of carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, purified water, sodium hydroxide, and xanthan gum.

Urea is a diamide of carbonic acid with the 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 of the skin.

Pharmacokinetics

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

INDICATIONS

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

This product is contraindicated in people with known or suspected hypersensitivity to any of the ingredients of the product.

WARNING

KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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. 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 will normally disappear

upon discontinuing the use of this product.

DOSAGE AND ADMINISTRATION

Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed.

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

STORAGE

Store at 20–25°C (68–77ºF), excursions permitted to 15–30ºC (59–86ºF). Protect from freezing and excessive heat. Keep bottle tightly closed

HOW SUPPLIED

28.35 g (1 oz.) bottles, NDC 39328-019-01

85 g (3 oz.) bottles, NDC 39328-019-03

198.4 g (7 oz.) bottles, NDC 39328-019-07

To report SUSPECTED ADVERSE REACTIONS, contact Patrin Pharma at 1-800-936-3088 or FDA at 1-800-FDA-1088 or www. fda.gov/medwatch for voluntary reporting of suspected adverse reactions.

Made in the USA
Manufactured for:
Patrin Pharma
Skokie, IL 60076
Questions (800) 936 3088

Rev 01.0525

PRINCIPAL DISPLAY PANEL - 28.35 g Bottle Carton

NDC 39328-019-01

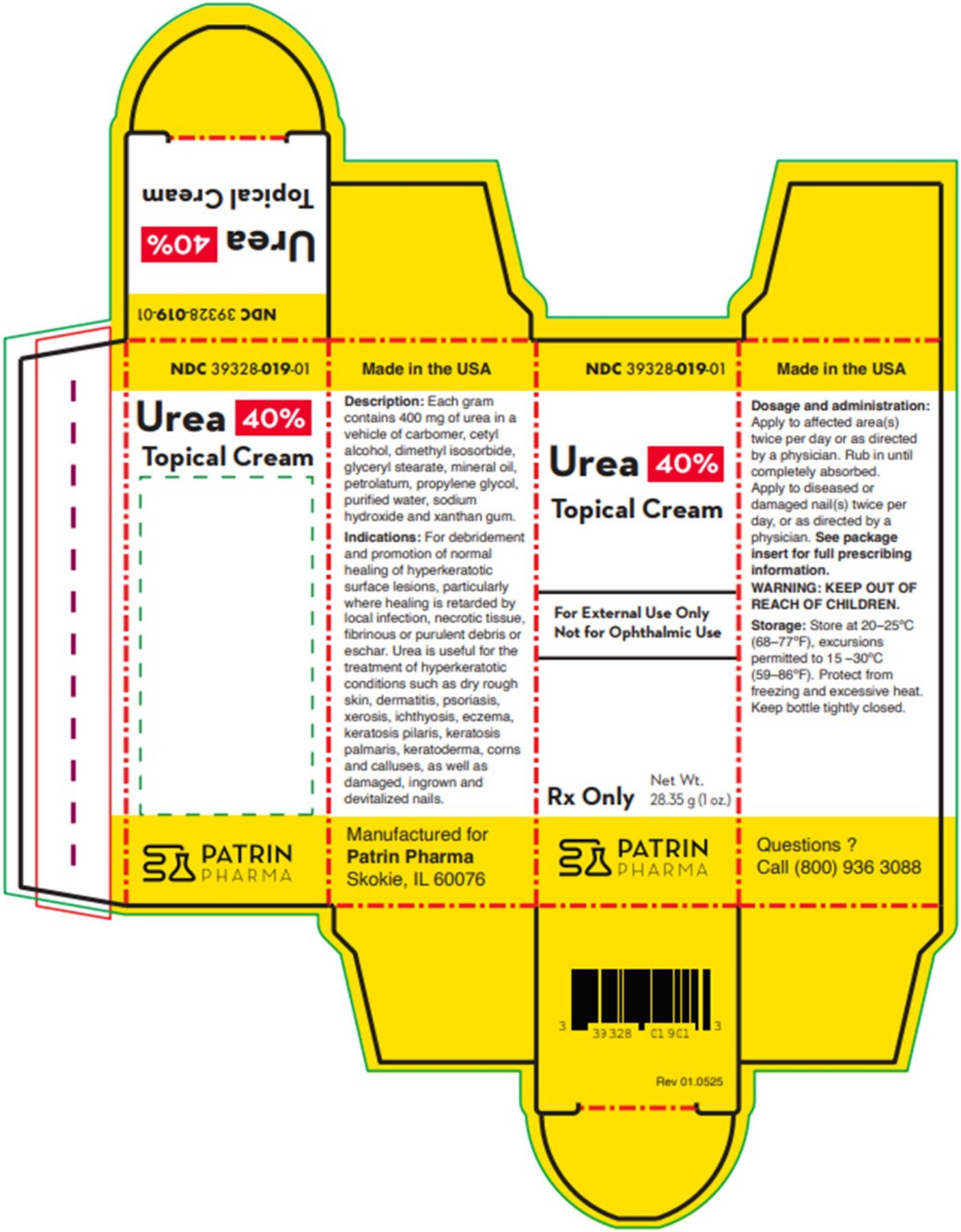
Urea 40%
Topical Cream

For External Use Only
Not for Ophthalmic Use

Rx Only

Net Wt.
28.35 g (1 oz.)

PATRIN
PHARMA


Urea 40%
Topical Cream
NDC 39328-019-01
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Made in the USA
Urea 40%
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Urea 40%
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Net Wt. 28.35 g (1 oz.)
Dosage and administration: Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail(s) twice per day, or as directed by a physician. See package insert for full prescribing information.
WARNING: KEEP OUT OF REACH OF CHILDREN.
Storage: Store at 20–25°C (68–77°F), excursions permitted to 15 –30°C (59–86°F). Protect from freezing and excessive heat. Keep bottle tightly closed.
PATRIN PHARMA
Manufactured for
Patrin Pharma
Skokie, IL 60076
PATRIN PHARMA
Questions ?
Call (800) 936 3088
3 39328 01901 3
Rev 01.0525

UREA 40%

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:39328-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Urea (UNII: 8W8T17847W) (Urea - UNII:8W8T17847W)	Urea	400 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Cetyl alcohol (UNII: 936JST6JCN)	
Dimethyl isosorbide (UNII: SA6A6V432S)	
Glyceryl monostearate (UNII: 230OU9XXE4)	
Mineral oil (UNII: T5L8T28FGP)	
Petrolatum (UNII: 4T6H12BN9U)	
Propylene glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
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:39328-019-01	1 in 1 CARTON	10/01/2025	
1		28.35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:39328-019-03	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2025	
3	NDC:39328-019-07	198.4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Unapproved drug other		10/01/2025	

Labeler - Patrin Pharma, Inc (806841677)

Revised: 8/2025 Patrin Pharma, Inc