UREA 39% CREAM- urea 39% cream cream
BioComp 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 CREAM 39%

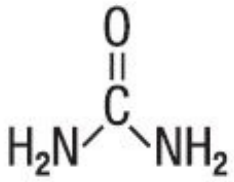
GENERAL:

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.

This product is a keratolytic emollient which is a gentle, yet potent, tissue softener for skin.

Each gram contains 390 mg of urea in a vehicle consisting of: carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, sodium hydroxide, water, and xanthan gum.

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



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.

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

INDICATIONS:

This product is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

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

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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.

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.

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.

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.

Transient stinging, burning, itching or irritation may occur and normally disappear upon discontinuing the use of this product.

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

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE:

Protect from freezing and excessive heat. Keep bottle tightly closed.

8 oz. (227 g) bottles, NDC 44523-801-08

To report a serious adverse event or obtain product information, call (866) 762-2365.

Manufactured for:
BIOCOMP PHARMA, INC.
San Antonio, TX 78230 1355

2100669 [00] R1021

NDC 44523-801-08 **Rx Only**

Urea 39%

Cream

Net wt. 8 oz. (227 g)

BioComp Pharma®

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INDICATIONS: This product is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

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

See package insert for full prescribing information.

WARNING: KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE. Avoid contact with eyes, lips and mucous membranes.

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

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UREA 39% CREAM

urea 39% cream cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:44523-801
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	390 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44523-801-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/23/2022	

Labeler - BioComp Pharma, Inc. (829249718)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(44523-801)

Revised: 3/2024 BioComp Pharma, Inc.