UREA- urea cream
AUSTIN PHARMACEUTICALS, LLC

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:

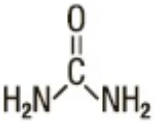
This product is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed. If redness or irritation occurs, discontinue use and consult a physician.

DESCRIPTION:

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:



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.

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.

CONTRAINDICATIONS:

This product is contraindicated in persons 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.

ADVERSE REACTIONS:

Transient stinging, burning, itching or irritation may occur and 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.

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). 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.

HOW SUPPLIED:

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

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.

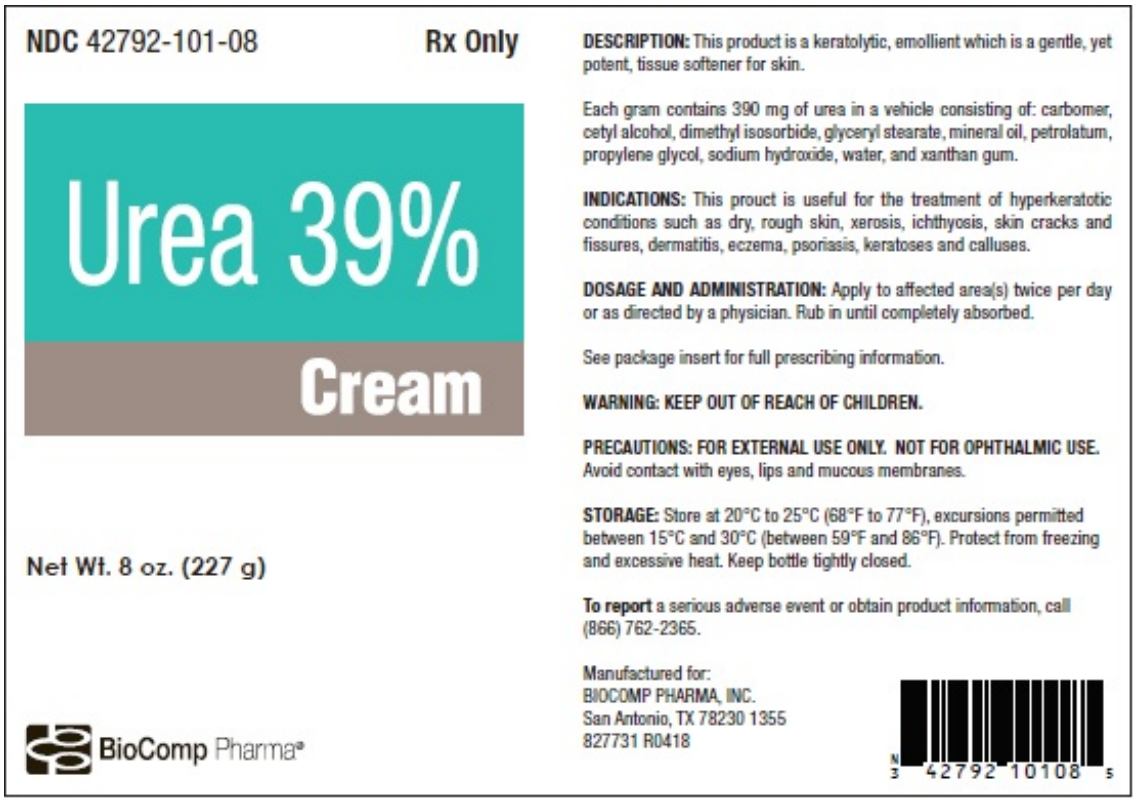
CARCINOGENISIS, MUTAGENESIS AND IMPAIRMENT OF FERTILITY:

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.

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.



UREA

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42792-101
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**
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
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:42792-101-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/09/2011	

Labeler - AUSTIN PHARMACEUTICALS, LLC (078398514)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(42792-101) , label(42792-101) , analysis(42792-101) , pack(42792-101)

Revised: 8/2022 AUSTIN PHARMACEUTICALS, LLC