UREA- urea 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 40% Cream

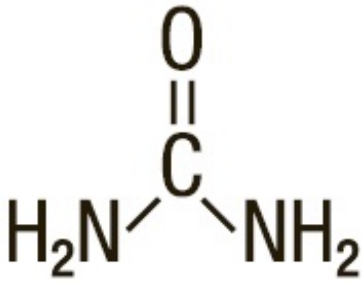
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram contains 400 mg of urea in a vehicle consisting 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 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.

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 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.

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 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°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.

HOW SUPPLIED:

1 oz. (28.35 g) bottles, **NDC** 44523-617-01
3 oz. (85 g) bottles, **NDC** 44523-617-03
7 oz. (198.4 g) bottles, **NDC** 44523-617-07

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

Manufactured for:
BIOCOMP PHARMA, INC.
San Antonio, TX 78230 1355
827650 R0218

NDC 44523-617-01 Rx Only

Urea 40%

Cream

Net Wt. 1 oz. (28.35 g)

BioComp Pharma®

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

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 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. Avoid contact with eyes, lips and mucous membranes.

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.

NDC 44523-617-01 Rx Only

Urea 40%

Cream

Net Wt. 1 oz. (28.35 g)

BioComp Pharma®

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.

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

Manufactured for:
BIOCOMP PHARMA, INC.
San Antonio, TX 78230 1355
827871 R0218

Serialization Label **F.P.O.**

N 3 44523 61701 8

NDC 44523-617-01 **Rx Only**

Urea 40%

Cream

Net Wt. 1 oz. (28.35 g)

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

DESCRIPTION: Each gram contains 400 mg of urea in a vehicle consisting of: carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, purified water, sodium hydroxide and xanthan gum.
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.
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.
To report a serious adverse event or obtain product information, call (866) 762-2365.
827646 R0218

N 3 44523 61701 8

NDC 44523-617-03 **Rx Only**

Urea 40%

Cream

Net Wt. 3 oz. (85 g)

BioComp Pharma®

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

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.

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.

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 and 30°C (between 59°F and 86°F). Protect from freezing and excessive heat. Keep bottle tightly closed.

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

Manufactured for:
BIOCOMP PHARMA, INC.
San Antonio, TX 78230 1355
827647 R0218

N 3 44523 61703 2

NDC 44523-617-07 **Rx Only**

Urea 40%

Cream

Net Wt. 7 oz. (198.4 g)

BioComp Pharma®

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

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.

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.

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 and 30°C (between 59°F and 86°F). Protect from freezing and excessive heat. Keep bottle tightly closed.

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Manufactured for:
BIOCOMP PHARMA, INC.
San Antonio, TX 78230 1355
827648 R0218

N 3 44523 61707 0

UREA

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:44523-617
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 INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MINERAL OIL (UNII: T5L8T28FGP)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44523-617-01	1 in 1 CARTON	03/15/2018	
1		28.35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:44523-617-03	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	
3	NDC:44523-617-07	198.4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/15/2018	

Labeler - BioComp Pharma, Inc. (829249718)

Revised: 4/2020 BioComp Pharma, Inc.