

UREA 40%- urea cream
Gabar Health Sciences Corp.

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

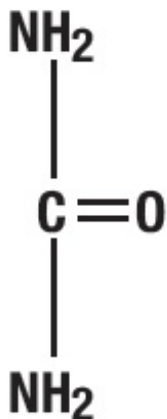
Rx Only

For external use only. Not for ophthalmic use.

Description

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: Water, Propylene Glycol, Glyceryl Stearate, Mineral Oil, Cetyl Alcohol, Carbomer, Petrolatum, Xanthan Gum and Sodium Hydroxide.

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 40% Cream 1 oz. (28.35 g): NDC 82429-308-15

Urea 40% Cream 3 oz. (85 g): NDC 82429-308-24

Urea 40% Cream 7 oz. (198.4 g): NDC 82429-308-25

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.

Manufactured for and distributed by:
Gabar Health Sciences Corp.
Atlanta, GA 30354

NDC 82429-308-15

Rx Only



UREA 40%

CREAM

Net Wt. 1 oz (28g)

INDICATIONS: 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.

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

See package insert for complete product information.

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Avoid contact with eyes, lips and mucous membranes

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

Urea 40% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin.

CAUTION: If redness or irritaiton occurs, discontinue use.

Each gram of Urea Cteam 40% contains Urea 40% and the following inactive ingredients: Water, Propylene Glycol, Glyceryl Stearate, Mineral Oil, Cetyl Alcohol, Carbomer, Petrolatum, Xanthan Gum, and Sodium Hydroxide.

Store at 20° to 25° C (68° to 77°F). See USP Controlled Room Temperature. Protect from freezing.

Manufactured for and distributed by:
Gabar Health Sciences Corp.
1 Hartsfield Center Parkway
Atlanta, GA 30354

Questions? 1-470-737-9424
www.gabarhealthsciences.com
Rev. 04-2023-00

LOT



NDC 82429-308-24

Rx Only



UREA 40%

CREAM

Net Wt. 3 oz (85g)

INDICATIONS: 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.

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

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Rev. 04-2023-00

LOT





UREA 40%

CREAM

Net Wt. 7 oz (198g)

INDICATIONS: 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.

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

See package insert for complete product information.

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Avoid contact with eyes, lips and mucous membranes

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

Urea 40% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin.

CAUTION: If redness or irritation occurs, discontinue use.

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Store at 20° to 25° C (68° to 77°F). See USP Controlled Room Temperature. Protect from freezing.

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Exp.



UREA 40%

urea cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:82429-308
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)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
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:82429-308-15	1 in 1 CARTON	08/01/2022	
1		28 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:82429-308-24	1 in 1 CARTON	08/01/2022	
2		85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:82429-308-25	1 in 1 CARTON	08/01/2022	
3		198 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2022	

Labeler - Gabar Health Sciences Corp. (118401847)

Registrant - Gabar Health Sciences Corp. (118401847)