

UREA- urea cream

AvPAK

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 40%

Rx Only

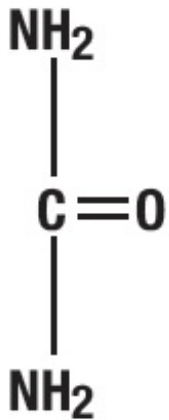
For external use only. Not for ophthalmic use.

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:

Carbomer, Cetearyl Alcohol, Glycerin,
Glyceryl Stearate SE, Mineral Oil, Purified Water,
White Petrolatum

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.

To report SUSPECTED ADVERSE REACTIONS contact AvKARE at 1-855-361-3993; email drugsafety@avkare.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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. tube (28.35 g) NDC 50268-872-28

3 oz. tube (85 g) NDC 50268-872-85

7 oz. bottle (198.4 g) NDC 50268-872-19

Store at room temperature 15°C - 30°C (59°F-86°F).

Protect from freezing. Keep bottle tightly closed.

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:

AvKARE

Pulaski, TN 38478

www.avkare.com

AV Rev. 6/22 Rev. 6/22

Tube Label

Rx Only

NDC 50268-872-28

UREA Cream 40%

For Topical use only
Not for ophthalmic use

AvKARE.

NET WT. 1 OZ. (28.35 g)

INGREDIENTS: Each gram of Urea Cream 40% contains Urea 40% and the following Inactive Ingredients: Carbomer, Cetearyl Alcohol, Glycerin, Glyceryl Stearate SE, Mineral Oil, Purified Water, White Petrolatum.

DOSAGE AND ADMINISTRATION: Use as directed by your physician.

See insert for full Prescribing Information.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

STORAGE: Store at room temperature
15°C-30°C (59°F-86°F).

Protect from freezing.

Do not use if foil seal is broken or missing.

Manufactured for:

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AV 06/22



UREA

urea cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50268-872
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-872-28	28.35 g in 1 TUBE; Type 0: Not a Combination Product	07/13/2022	
2	NDC:50268-872-19	198.4 g in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2023	
3	NDC:50268-872-85	85 g in 1 TUBE; Type 0: Not a Combination Product	02/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/13/2022	

Labeler - AvPAK (832926666)

Revised: 2/2023

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