UREA CREAM 40%- urea cream
Akron 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 40%

Urea 40%

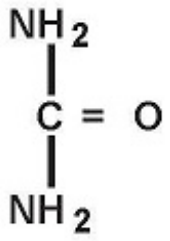
Rx Only

For topical use only.

Not for ophthalmic use.

Description

Each gram contains 400 mg of urea in a vehicle consisting of:
cetyl alcohol, glycerin monostearate, phosphomer X-polymer, mineral oil, propylene glycol, purified water, trolamine 99%, white petrolatum, xanthan gum.



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 eshar. 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.

KEEP OUT OF REACH OF CHILDREN.

Precautions

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

PREGNANACY

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 a serious adverse event or obtain product information, call 1-877-255-6999.

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.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each person's professional opinion and knowledge, upon evaluation of the active ingredients, excipients, inactive ingredients and chemical information provided herein.

How Supplied

Urea 40% Cream 1 oz.(28.35 g): NDC 71399-8456-1; Urea 40% Cream 3 oz.(85 g): NDC NDC 71399-8456-3; Urea 40% Cream 7 oz.(198.45 g): NDC NDC 71399-8456-7

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.

Manufactured for:
Akron Pharma Inc.,
Fairfield, NJ-07004
www.akronpharma.com

Manufactured In USA

DESCRIPTION:
Each gram contains 400 mg of urea in a vehicle consisting of: cetyl alcohol, glycerin monostearate, phosphomer X-polymer, mineral oil, propylene glycol, purified water, trolamine 99%, white petrolatum, 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.

To report a serious adverse event or obtain product information, call 1-877-255-6999.

NDC 71399-8456-1

Urea Cream 40%

For topical use only
Not for ophthalmic use

Rx Only

Akron Pharma

NET WT. 1 OZ (28 g)

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.

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.

Rev.:07/22

Manufactured for:
Akron Pharma Inc.,
Fairfield, NJ-07004
www.akronpharma.com
Manufactured In USA

N 3 71399 84561 0

NDC 71399-8456-3

Urea Cream 40%

For topical use only
Not for ophthalmic use

Rx Only

Akron Pharma

NET WT. 3 OZ(85 g)

DESCRIPTION:
Each gram contains 400 mg of urea in a vehicle consisting of: cetyl alcohol, glyceryl monostearate, mineral oil, phosphomer X-polymer, propylene glycol, purified water, trolamine 99%, white petrolatum, 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.

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.

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 1-877-255-6999.

Rev.:07/22

Manufactured for:
Akron Pharma Inc.,
Fairfield, NJ-07004
www.akronpharma.com
Manufactured In USA

N 3 71399 84563 4

NDC 71399-8456-7

Urea Cream 40%

For topical use only
Not for ophthalmic use

Rx Only

Akron Pharma NET WT. 7 OZ(198.4 g)

DESCRIPTION:
Each gram contains 400 mg of urea in a vehicle consisting of: cetyl alcohol, glycerin monostearate, phosphomer X-polymer, mineral oil, propylene glycol, purified water, trolamine 99%, white petrolatum, 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 1-877-255-6999.

Rev.:07/22
Akron Pharma
Manufactured for:
Akron Pharma Inc.,
Fairfield, NJ-07004
www.akronpharma.com
Manufactured In USA

N 3 71399 84567 2

UREA CREAM 40%

urea cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71399-8456
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8456-1	28.35 g in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2024	
2	NDC:71399-8456-3	85 g in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2024	
3	NDC:71399-8456-7	198.45 g in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2024	

Labeler - Akron Pharma Inc. (067878881)

Revised: 9/2024 Akron Pharma Inc.