

UREA 39.5% WITH 2% SALICYLIC ACID- urea, salicylic acid cream

PureTek Corporation

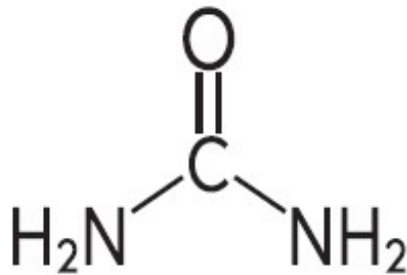
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

Urea 39.5% Cream with 2% Salicylic Acid

DESCRIPTION

Urea 39.5% Cream with 2% Salicylic Acid is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin space. Each gram contains 395 mg of urea, 20 mg of Salicylic Acid in vehicle consisting of: Aqua (Purified Water), Butylene Glycol, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Methylparaben, Mineral Oil, Petrolatum, Polysorbate 60, Propylparaben, Simethicone, Sodium Hydroxide, Squalane, Stearic Acid.

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 & 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 dermatitis, psoriasis, soothes rough and dry skin, 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.

WARNINGS

FOREXTERNALUSEONLY.NOTFOR OPHTHALMIC USE. KEEP OUT OF REACH OF CHILDREN.

Avoid contact with eyes, lips and mucous membranes. When using this product skin irritation and dryness is more likely to occur.

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 medication.

DOSAGE AND ADMINISTRATION

Apply Urea 39.5% Cream with 2% Salicylic Acid 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 39.5% Cream with 2% Salicylic Acid 8 oz. (227 g): NDC 59088-210-16

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat. Keep container tightly closed.

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

Urea 39.5% Cream™ with 2% Salicylic Acid

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

Active Ingredients: Urea 39.5% - Salicylic Acid 2%
Inactive Ingredients: Aqua (Purified Water), Butylene Glycol, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Dimethicone, Disodium EDTA, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Methylparaben, Mineral Oil, Petrolatum, Polysorbate 60, Propylparaben, Simethicone, Sodium Hydroxide, Squalane, Stearic Acid.

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. For the treatment of hyperkeratotic conditions such as dermatitis, psoriasis, soothes rough and dry skin, xerosis, ichthyosis, eczema, keratosis pilaris, keratosis palmaris, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.

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Dosage and Administration: Apply Urea 39.5% Cream with 2% Salicylic Acid to affected area(s) 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.

When using this product avoid contact with eyes, lips or mucous membranes.

NDC 59088-210-16

Rx Only

DERMACIN[®]

Urea 39.5% Cream™
with 2% Salicylic Acid

Soothes and Hydrates
FOR DRY, ROUGH, CRACKED,
AND CALLUSED SKIN

Use under the direction of a medical practitioner.
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

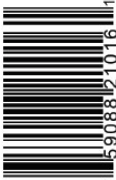
8oz (227g)

BL4 - MINIMUM NO VARNISH
AREA = 12.5 mm x 38 mm
FOR POSITION ONLY
DO NOT PRINT

Discontinue use and consult a physician if redness or irritation occurs.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat. Keep container tightly closed.

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PureTek Corporation
Panorama City, CA 91402
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List No: 21016IAA
Rev No: 38629



UREA 39.5% WITH 2% SALICYLIC ACID

urea, salicylic acid cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	39.5 g in 100 g
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-210-16	227 g in 1 JAR; Type 0: Not a Combination Product	03/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/24/2023	

Labeler - PureTek Corporation (785961046)

Revised: 3/2023

PureTek Corporation