

URACIN 20%- urea 20% 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.

Uracin 20% Cream

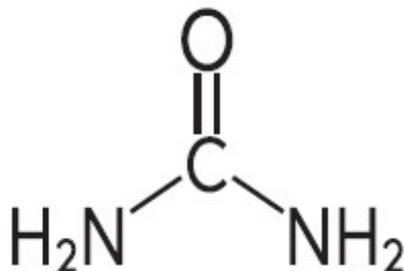
Rx only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION

Uracin 20% Cream is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram contains 200 mg of urea in a vehicle consisting of the following inactive ingredients : Aqua (Purified Water), Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Cetareth-20, Cetearyl Alcohol, Citric Acid, Cocos Nucifera (Coconut) Oil, Dimethicone, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Seed Oil, Laureth-7, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Xanthan Gum.

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. Soothes rough and dry skin.

CONTRAINDICATIONS

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

WARNINGS

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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

If swallowed, get medical help or contact a Poison Control Center right away.

Avoid contact with eyes, lips and mucous membranes.

General

This product is to be used as directed by a licensed healthcare practitioner 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 licensed healthcare practitioner.

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 **Uracin 20% Cream** to affected area twice per day, or as directed by a licensed healthcare practitioner.

Rub in until completely absorbed.

Apply to diseased or damaged nail(s) twice per day, or as directed by a licensed healthcare practitioner.

HOW SUPPLIED

Uracin™ 20% cream is supplied in a 8 oz.(227 g) jar, NDC 59088-257-16

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.

To report side effects, call **PureTek Corporation at 1-877-921-7873.**

Uracin™ 20% Cream

<p>Active Ingredient: Urea 20%</p> <p>Inactive Ingredients: Aqua (Purified Water), Butyrospermum parkii (Shea) Butter, C13-14 Isoparaffin, Ceteareth-20, Cetearyl Alcohol, Citric Acid, Cocos Nucifera (Coconut) Oil, Dimethicone, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Helianthus annuus (Hybrid Sunflower) seed oil, Laureth-7, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Xanthan gum.</p> <p>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 dry, rough skin, dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis pilaris, keratosis palmaris, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.</p> <p>Contraindications: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.</p> <p>Dosage and Administration: Apply Uracin™ 20% Cream to affected area(s) twice per day, or as directed by your licensed healthcare practitioner. Rub in until completely absorbed. Apply to diseased or damaged nail(s) twice per day, or as directed by a licensed healthcare practitioner.</p> <p>When using this product avoid contact with eyes, lips or mucous membranes.</p>	<p>NDC 59088-257-16</p> <p>Rx Only</p> <p>DERMACIN[®]</p> <p>Uracin™ 20% Cream</p> <p>Urea 20%</p> <p>Soothes and Hydrates Dry Cracked Skin FOR DRY, ROUGH, CRACKED, AND CALLUSED SKIN</p> <p>Use under the direction of a licensed healthcare practitioner.</p> <p>FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.</p> <p>8oz (227g)</p>	<p>Discontinue use and consult a licensed healthcare practitioner if redness or irritation occurs. Keep this and all medications out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Manufactured in the USA by: PureTek Corporation Panorama City, CA 91402 For questions or information call toll-free: 877-921-7873</p> <p>List No: 25716IGA Rev No: 39270</p> 
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Panorama City, CA 91402
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URACIN 20% urea 20% cream			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-257

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
CETEARETH-20 (UNII: YRC528SWJY)	
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0073W7L)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL (UNII: 3W1JG795YI)	
WATER (UNII: 059QF0K0OR)	
LAURETH-7 (UNII: Z95S6G8201)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER (120000 MPA.S AT 1%) (UNII: 5F4963KLHS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-257-16	227 g in 1 JAR; Type 0: Not a Combination Product	02/20/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/20/2026	

Labeler - PureTek Corporation (785961046)