

UREA 41- urea 41 cream
Oncora Pharma, LLC

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 41% 85477-306-27

DESCRIPTION

Urea 41% Cream used to soften and moisturize dry, rough, and hyperkeratotic skin.

INDICATIONS AND USAGE

Urea 41% Cream is indicated 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.

It is also indicated for the treatment of hyperkeratotic conditions such as:

- dry, rough skin
- dermatitis
- psoriasis
- xerosis
- ichthyosis
- eczema
- keratosis pilaris
- keratosis palmaris
- keratoderma
- corns and calluses
- damaged, ingrown, or devitalized nails

WARNINGS

For external use only.

Avoid contact with eyes, lips, or mucous membranes.

Discontinue use and consult a physician if redness, irritation, or sensitivity occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

DOSAGE AND ADMINISTRATION

Apply Urea 41% Cream to affected area(s) twice daily or as directed by a physician.

Rub into the skin until completely absorbed.

For nail conditions, apply to diseased or damaged nails twice daily or as directed by a

physician.

HOW SUPPLIED

Urea 41% Cream is supplied as:

8 oz (227 g) container

NDC: **85477-306-27**

Dispensed by prescription.

PRINCIPAL DISPLAY PANEL

Urea Cream 41%

For dry, rough, cracked, and callused skin.

For external use only. Not for ophthalmic use.

8 oz (227 g)

Distributed by:

Oncora Pharma

Dallas, TX 75161

Active Ingredients: Urea 41%

Inactive Ingredients: Water (Aqua), Urea, Cetearyl Alcohol, Propylene Glycol, Cetareth-20, Paraffin, Polyacrylamide, Xanthan Gum, C13-14 Isoalkane, Laureth-7, Phenoxyethanol, Ethylhexylglycerin.

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

Dosage and Administration: Apply Urea 41% Cream to affected area(s) twice per day, or as directed by your physician. Rub 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.

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, lichenosis, eczema, keratosis pilaris, keratosis palmars, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.



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 - 77F) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat. Keep container tightly closed.

Distributed by:
Oncora Pharma
Dallas, TX, 75161
© 2026 Oncora Pharma



pdp

UREA 41

urea 41 cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85477-306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	41 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETEARETH-20 (UNII: YRC528SWJY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-306-27	227 g in 1 JAR; Type 0: Not a Combination Product	03/06/2026	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/06/2026	

Labeler - Oncora Pharma, LLC (119482542)