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

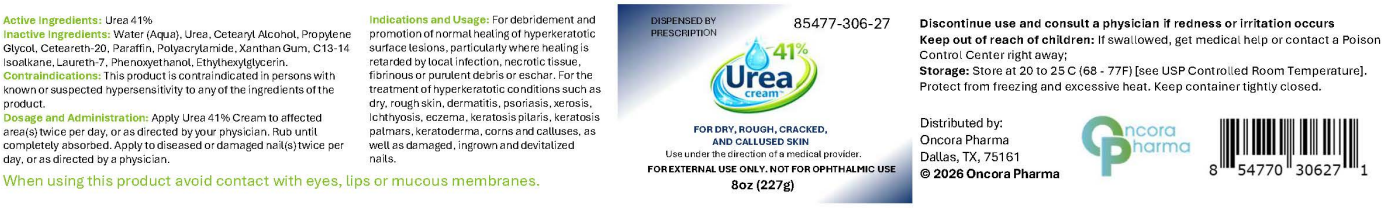
Urea Cream 41%

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



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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)

Revised: 3/2026 Oncora Pharma, LLC