UREA 41%- urea 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% Cream

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 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

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

WARNINGS

Avoid contact with eyes, lips and mucous membranes.

ADVERSE REACTIONS:

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

DOSAGE AND ADMINISTRATION

Apply Urea 41% 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

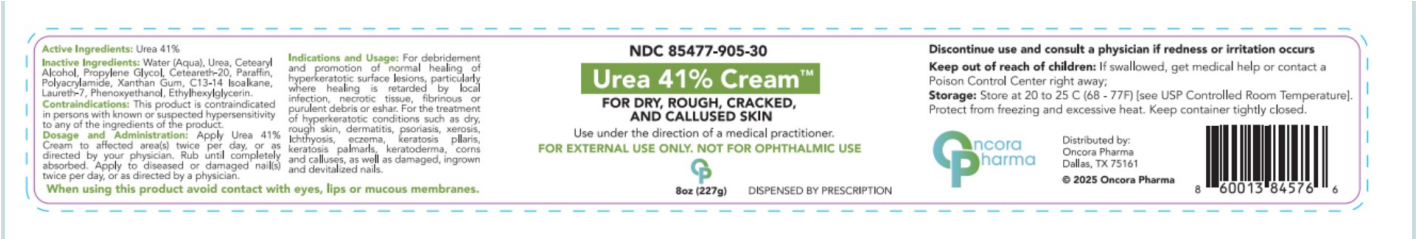
Urea 41% Cream 8 oz. (227 g): NDC 85477-905-30

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 41% Cream™



Distributed by

Oncora Pharma

Dallas, TX 75161

UREA 41%

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:85477-905
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	410 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETEARETH-20 (UNII: YRC528SWJY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LAURETH-7 (UNII: Z95S6G8201)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:85477-905-30	227 g in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/11/2025	

Labeler - Oncora Pharma, LLC (119482542)

Revised: 6/2025

Oncora Pharma, LLC