

**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](#).*

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**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 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.

**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™

**Active Ingredients:** Urea 41%

**Inactive Ingredients:** Water (Aqua), Urea, Cetearyl Alcohol, Propylene Glycol, Ceteareth-20, Paraffin, Polyacrylamide, Xanthan Gum, C13-14 Isokane, 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 nails 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, ichthyosis, eczema, keratosis pilaris, keratosis palmaris, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.


NDC 85477-905-30

**Urea 41% Cream™**

**FOR DRY, ROUGH, CRACKED, AND CALLUSED SKIN**

Use under the direction of a medical practitioner.


**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE**


 **Box (227g)**    **DISPENSED BY PRESCRIPTION**

**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  
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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)