

## **UREA CREAM 40%- urea cream**

### **Major Pharmaceuticals**

*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 Cream 40%**

#### **Urea 40%**

Rx Only

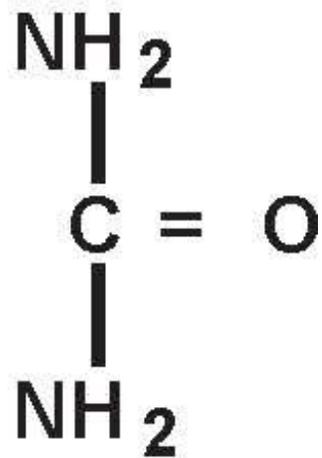
For topical use only.

Not for ophthalmic use.

#### **Description**

Urea 40% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of Urea 40% contains 40% urea as an active ingredient, and the following inactive ingredients: Cetareth-6, Cetareth-25, Cetyl Alcohol, Mineral Oil, Propylene Glycol, Purified Water, Sodium Hydroxide, Stearyl Alcohol, 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.

## **Contraindications**

Known hypersensitivity to any of the listed ingredients.

## **Warnings**

For topical use only. Avoid contact with eyes, lips or mucous membranes.

## **Precautions**

This medication is to be used as directed by a physician 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 physician.

## **PREGNANCY**

Pregnancy Category B. Animal reproduction studies have revealed no evidence of harm to the fetus, however, there are no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, Urea 40% should be given to a pregnant woman only if clearly needed.

## **NURSING MOTHERS**

It is not known whether or not this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Urea 40% is administered to a nursing woman.

## **Adverse Reactions**

Transient stinging, burning, itching or irritation may occur and normally disappear upon discontinuing the medication.

## **Dosage and Administration**

Apply Urea 40% 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.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each person's professional opinion and knowledge, upon evaluation of the active ingredients, excipients, inactive ingredients and chemical information provided herein.

## **How Supplied**

Urea 40% Cream 1 oz.(28.35 g): NDC 0904-7167-23; Urea 40% Cream 3 oz.(85 g): NDC 0904-7167-83; Urea 40% Cream 7 oz.(198.4 g): NDC 0904-7167-99. Store at room temperature 15°C - 30°C (59°F - 86°F). Protect from freezing. Keep bottle tightly closed.

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

Cetareth-6, Cetareth-25, Cetyl Alcohol, Mineral Oil, Propylene Glycol, Purified Water,

Sodium Hydroxide, Stearyl Alcohol, Xanthan Gum

MAJOR<sup>®</sup>

NDC 0904-7167

Urea Cream 40%

For topical use only

Not for ophthalmic use

Rx Only

**DOSAGE AND ADMINISTRATION:** Use as directed by your physician. See insert for full prescribing information.

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

For lot number and expiration date, see bottom of bottle.

Distributed by:

MAJOR<sup>®</sup> PHARMACEUTICALS

Livonia, MI 48152

Rev. 01/23

All prescription substitutions and / or recommendations using this product shall be made subject to state and federal statutes as applicable. Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency. Please see package insert for more details.

**INGREDIENTS:** Each gram of Urea 40% contains 40% Urea as an active ingredient, and the following inactive ingredients: Cetareth-6, Cetareth-25, Cetyl Alcohol, Mineral Oil, Propylene Glycol, Purified Water, Sodium Hydroxide, Stearyl Alcohol, Xanthan Gum.

**DOSAGE AND ADMINISTRATION:**  
Use as directed by your physician. See insert for full prescribing information.

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



**MAJOR®**

**NDC 0904-7167-23**

**Urea  
Cream 40%**

For topical use only  
Not for ophthalmic use

**Rx Only 1 oz. (28.35 g)**

**STORAGE:** Store at room temperature 15°C-30°C (59°F-86°F).  
Protect from freezing.  
Keep bottle tightly closed.

For lot number and expiration date, see bottom of bottle.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Please see package insert for more details.

Rev. 05/21

**Distributed by:**  
**MAJOR® PHARMACEUTICALS**  
Livonia, MI 48152

**MAJOR®**

**NDC 0904-7167-23**

**Urea  
Cream 40%**

For topical use only  
Not for ophthalmic use

**Rx Only 1 oz. (28.35 g)**

<p><b>INGREDIENTS:</b> Each gram of Urea 40% contains 40% Urea as an active ingredient, and the following inactive ingredients: Cetareth-6, Cetareth-25, Cetyl Alcohol, Mineral Oil, Propylene Glycol, Purified Water, Sodium Hydroxide, Stearyl Alcohol, Xanthan Gum.</p> <p><b>DOSAGE AND ADMINISTRATION:</b> Use as directed by your physician. See insert for full prescribing information.</p> <p><b>KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.</b></p>  <p>3 09047 16783 8</p>	<p><b>MAJOR<sup>®</sup></b></p> <p><b>NDC 0904-7167-83</b></p> <p><b>Urea Cream 40%</b></p> <p>For topical use only Not for ophthalmic use</p> <p><b>Rx Only 3 oz. (85 g)</b></p>	<p><b>STORAGE:</b> Store at room temperature 15°C-30°C (59°F-86°F). Protect from freezing. Keep bottle tightly closed.</p> <p>For lot number and expiration date, see bottom of bottle.</p> <p>All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. <b>Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.</b> Please see package insert for more details.</p> <p>Rev. 05/21</p> <p><b>Distributed by:</b> <b>MAJOR<sup>®</sup> PHARMACEUTICALS</b> Livonia, MI 48152</p>	<p><b>MAJOR<sup>®</sup></b></p> <p><b>NDC 0904-7167-83</b></p> <p><b>Urea Cream 40%</b></p> <p>For topical use only Not for ophthalmic use</p> <p><b>Rx Only 3 oz. (85 g)</b></p>
---	---	--	---

## UREA CREAM 40%

urea cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0904-7167
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>UREA</b> (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	400 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	

<b>CETEARETH-6</b> (UNII: 2RJS3559D3)	
<b>CETEARETH-25</b> (UNII: 8FA93U5T67)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7167-83	1 in 1 CARTON	07/06/2021	03/28/2026
1		85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0904-7167-23	1 in 1 CARTON	07/06/2021	03/28/2026
2		28.35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0904-7167-99	1 in 1 CARTON	10/04/2023	03/28/2026
3		198.4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/06/2021	03/28/2026

**Labeler** - Major Pharmaceuticals (191427277)