UREA 40 PERCENT- urea cream
Method Pharmaceuticals, 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 40 Percent Cream

DESCRIPTION:

INGREDIENTS: Each gram

of Urea Cream 40%

contains Urea 40% and the

following inactive

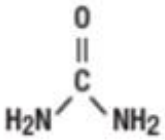
ingredients: Carbomer,

Cetearyl Alcohol, Glycerin,

Glyceryl Stearate SE,

Mineral Oil, Purified Water,

White Petrolatum.



CLINICAL PHARMACOLOGY:

Urea gently dissolves the intercellular matrix which results in loosening the horny layer of skin and shedding 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:

This product is useful for the treatment of hyperkeratotic

conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

CONTRAINDICATIONS:

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

WARNINGS:

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE. KEEP OUT OF REACH OF CHILDREN.

Avoid contact with eyes, lips and mucous membranes.

General:

This product 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.

Information for Patients:

Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. Avoid contact with eyes, lips and mucous membranes.

Carcinogenesis, Mutagenesis and Impairment of Fertility:

Long-term animal studies for carcinogenic potential have not been performed on this product to date.
Studies on reproduction and fertility also have not been performed.

Pregnancy:

Category C. Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers:

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

ADVERSE REACTIONS:

Transient stinging, burning, itching or irritation may occur and normally disappear upon discontinuing the use of this product.

DOSAGE AND ADMINISTRATION:

Use as
directed by your physician.
See label booklet for full
Prescribing Information.

STORAGE:

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

HOW SUPPLIED:

This product is supplied in the following size(s): 3 oz, 1 oz, and 7oz

To report a serious adverse event or obtain product information, call 877-250-3427

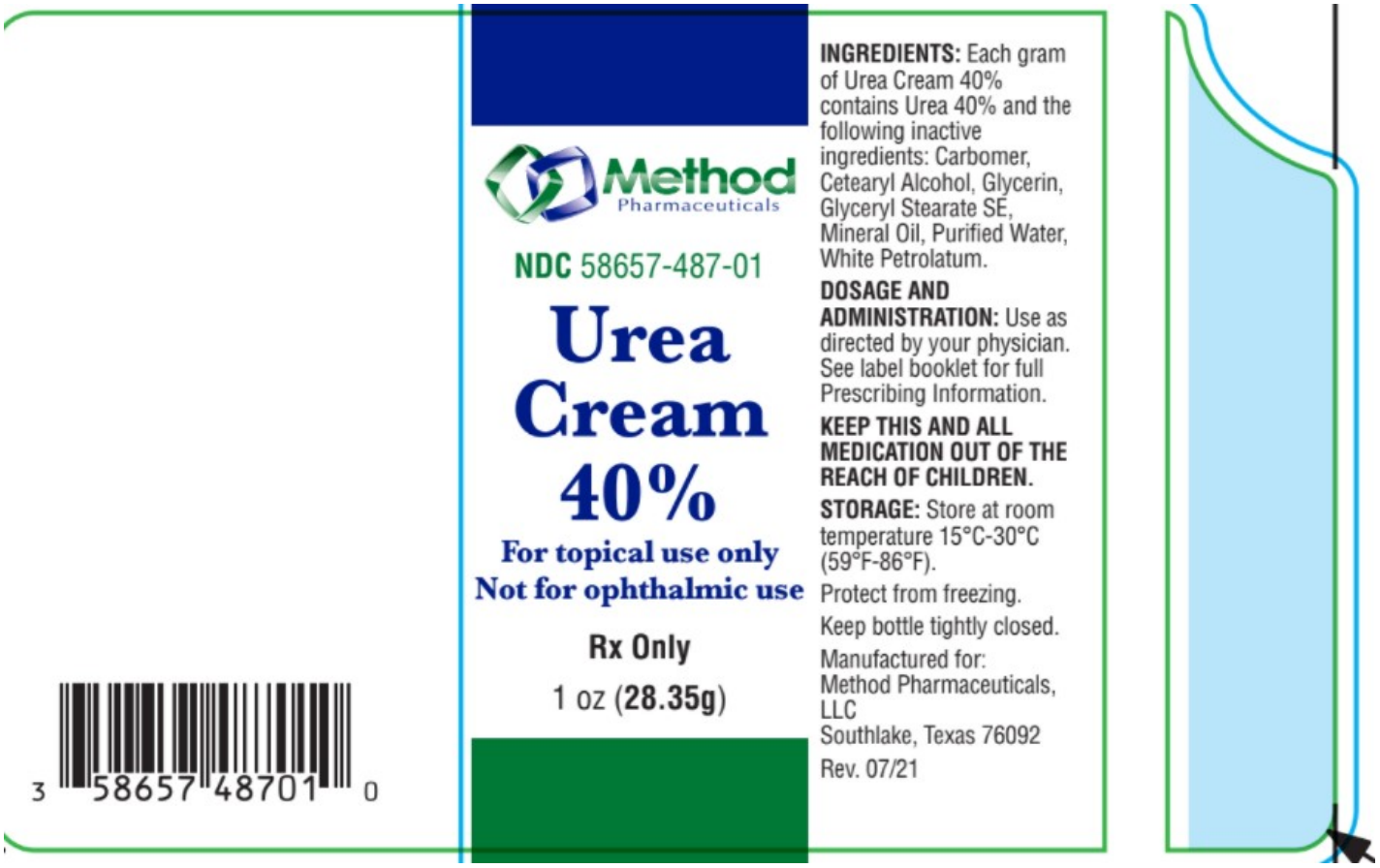
To report a serious adverse event, please contact Method Pharmaceuticals at (877) 250-3427; email at contact@methodpharm.com; or call FDA at (800) FDA-1088.

Manufactured for:

Method Pharmaceuticals, LLC Fort Worth, Texas 76118

Rev. 11/21

PRINCIPAL DISPLAY PANEL


Method
Pharmaceuticals
NDC 58657-487-01
Urea Cream 40%
For topical use only
Not for ophthalmic use
Rx Only
1 oz (28.35g)
INGREDIENTS: Each gram of Urea Cream 40% contains Urea 40% and the following inactive ingredients: Carbomer, Cetearyl Alcohol, Glycerin, Glyceryl Stearate SE, Mineral Oil, Purified Water, White Petrolatum.
DOSAGE AND ADMINISTRATION: Use as directed by your physician. See label booklet for full Prescribing Information.
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
STORAGE: Store at room temperature 15°C-30°C (59°F-86°F).
Protect from freezing.
Keep bottle tightly closed.
Manufactured for:
Method Pharmaceuticals, LLC
Southlake, Texas 76092
Rev. 07/21
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Method Pharmaceuticals

NDC 58657-487-03

Urea Cream 40%

For topical use only

Not for ophthalmic use

Rx Only

3 oz (**85g**)

INGREDIENTS: Each gram of Urea Cream 40% contains Urea 40% and the following inactive ingredients: Carbomer, Cetearyl Alcohol, Glycerin, Glyceryl Stearate SE, Mineral Oil, Purified Water, White Petrolatum.

DOSAGE AND ADMINISTRATION: Use as directed by your physician. See label booklet for full Prescribing Information.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

STORAGE: Store at room temperature 15°C-30°C (59°F-86°F).

Protect from freezing.

Keep bottle tightly closed.

Manufactured for:
Method Pharmaceuticals, LLC
Southlake, Texas 76092

Rev. 07/21

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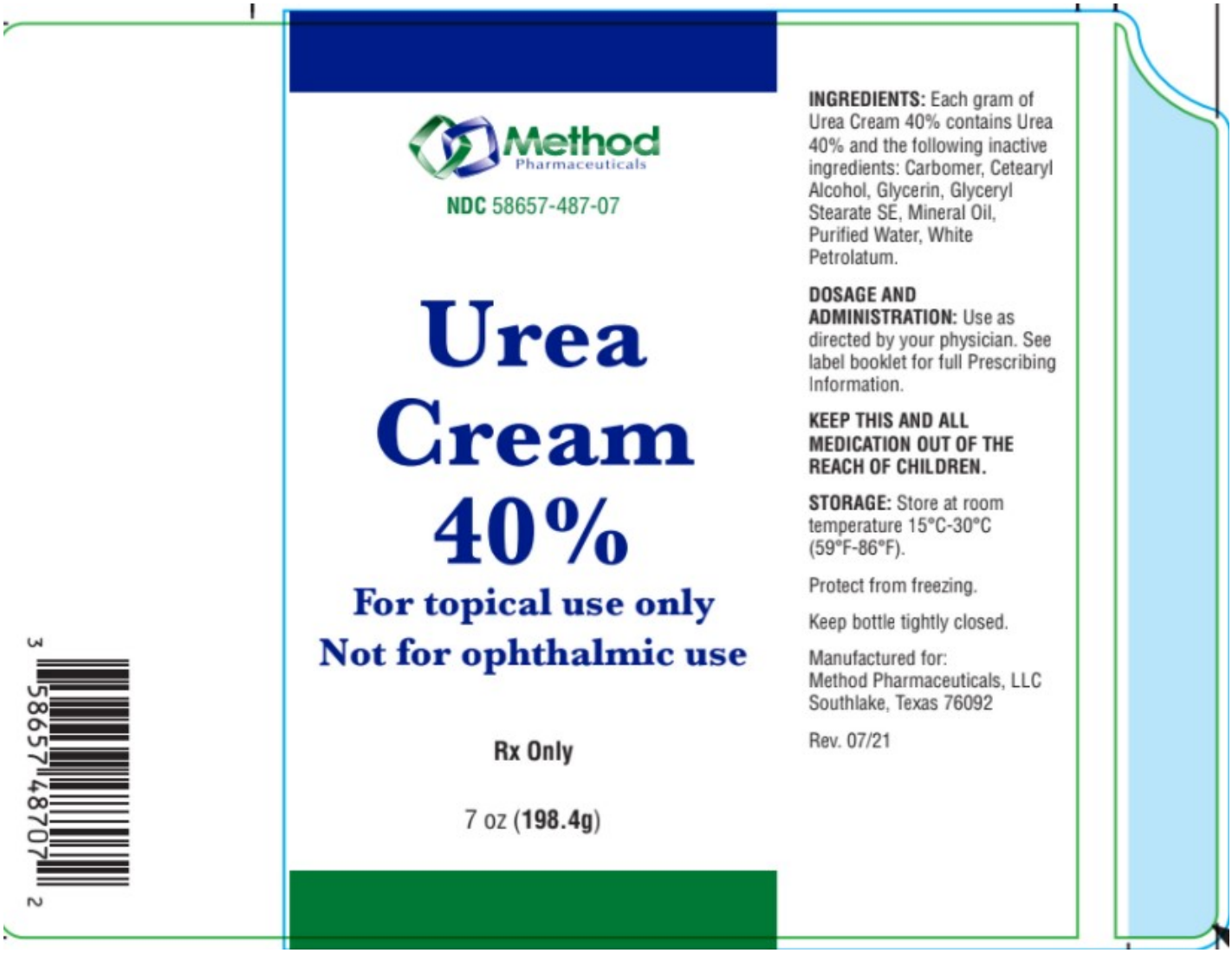

UREA 40 PERCENT

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58657-487
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	400 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-487-07	198.4 g in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2021	
2	NDC:58657-487-01	28.35 g in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2021	
3	NDC:58657-487-03	85 g in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/15/2021	

Labeler - Method Pharmaceuticals, LLC (060216698)

Revised: 12/2023 Method Pharmaceuticals, LLC