**UREA CREAM 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.*

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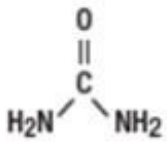
**Urea 40 Percent Cream**

## 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:

Carbomer, Cetearyl Alcohol, Glycerin, Glyceryl Stearate SE, Mineral Oil, Purified Water, White Petrolatum.

Urea is a diamide of carbonic acid with the following chemical structure:




## 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 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 use of this product.

**To report SUSPECTED ADVERSE REACTIONS, contact Method Pharmaceuticals, LLC at**

**1-877-250-3427; or FDA at 1-800-FDA-1088 or** www.fda.gov/medwatch**.**

## 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.

## How Supplied

Urea 40% Cream

1 oz. (28.35 g): NDC 58657-489-01

Urea 40% Cream

3 oz. (85 g): NDC 58657-489-03

Urea 40% Cream

7 oz. (198.4 g): NDC 58657-489-07

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.**

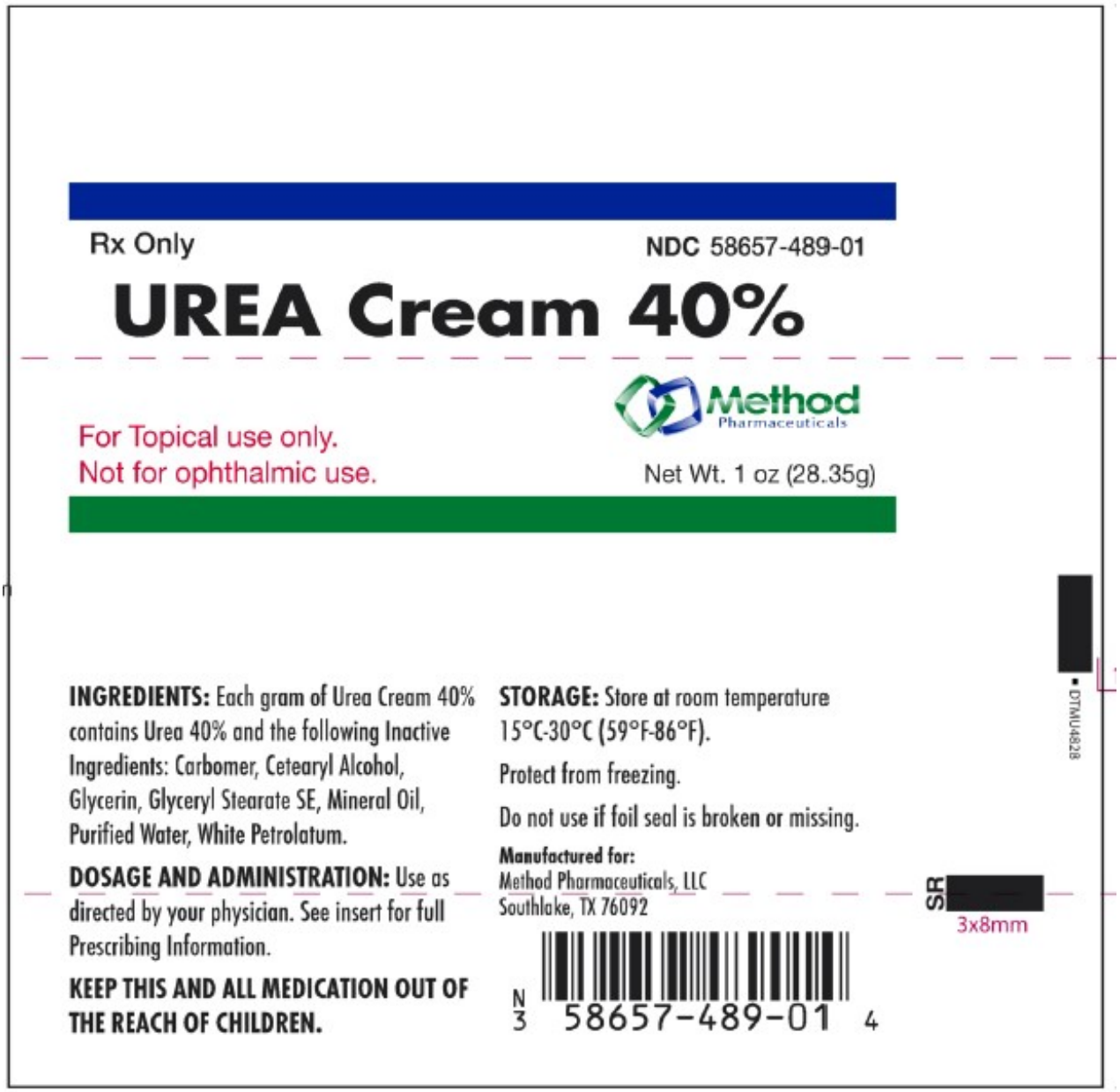
Manufactured for:

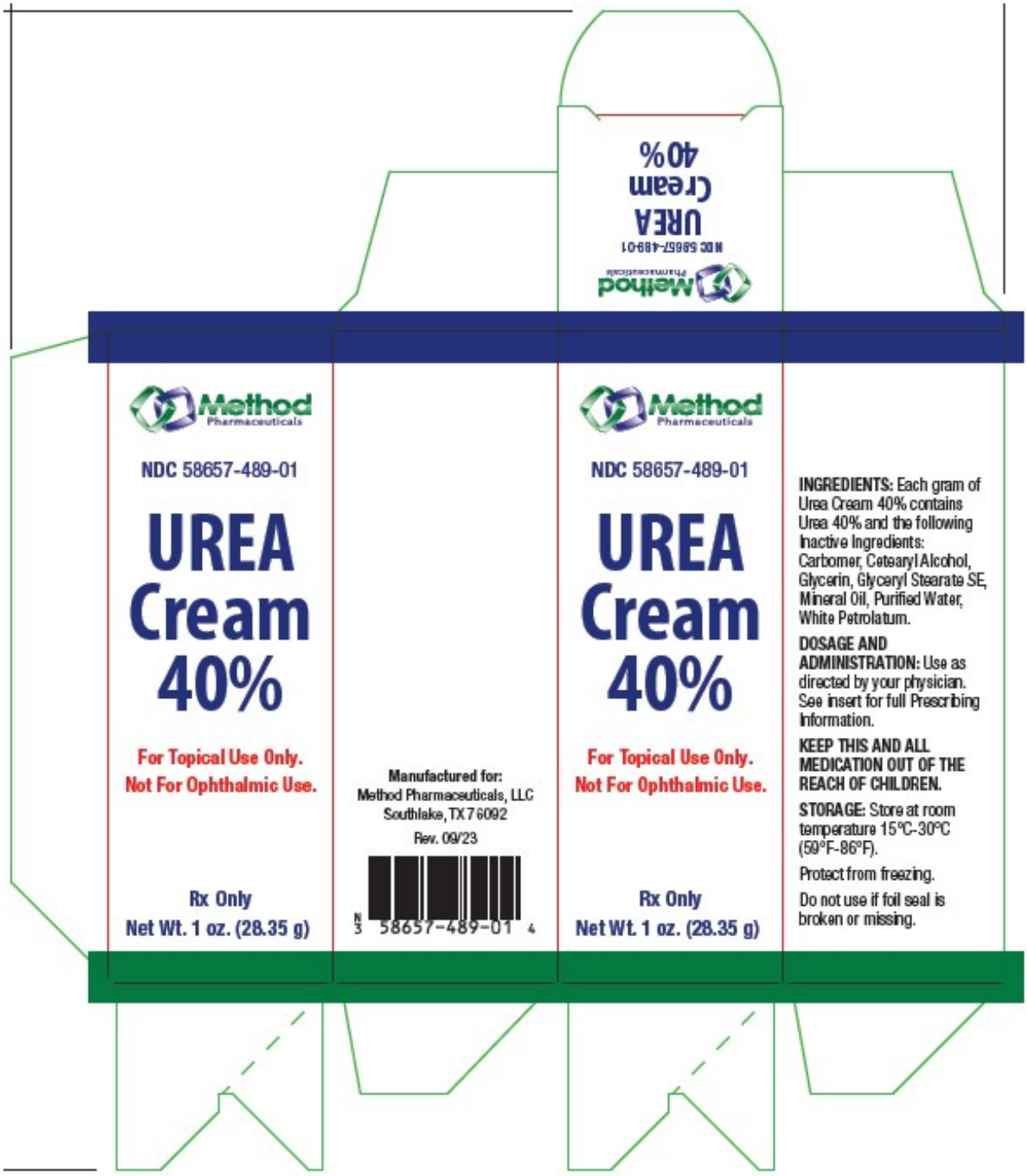
**Method Pharmaceuticals, LLC**

Southlake, Texas 76092

Rev. 09/23

**PRINCIPAL DISPLAY PANEL**




UREA
Cream
40%
NDC 58657-489-01
Method
Pharmaceuticals
NDC 58657-489-01
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Cream
40%
For Topical Use Only.
Not For Ophthalmic Use.
Rx Only
Net Wt. 1 oz. (28.35 g)
Manufactured for:
Method Pharmaceuticals, LLC
Southlake, TX 76092
Rev. 09/23
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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 insert 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.
Do not use if foil seal is broken or missing.

Rx Only

NDC 58657-489-03

# UREA Cream 40%

Method Pharmaceuticals

For Topical use only. Not for ophthalmic use.

Net Wt. 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 insert 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.

Do not use if foil seal is broken or missing.

**Manufactured for:**
Method Pharmaceuticals, LLC
Southlake, TX 76092

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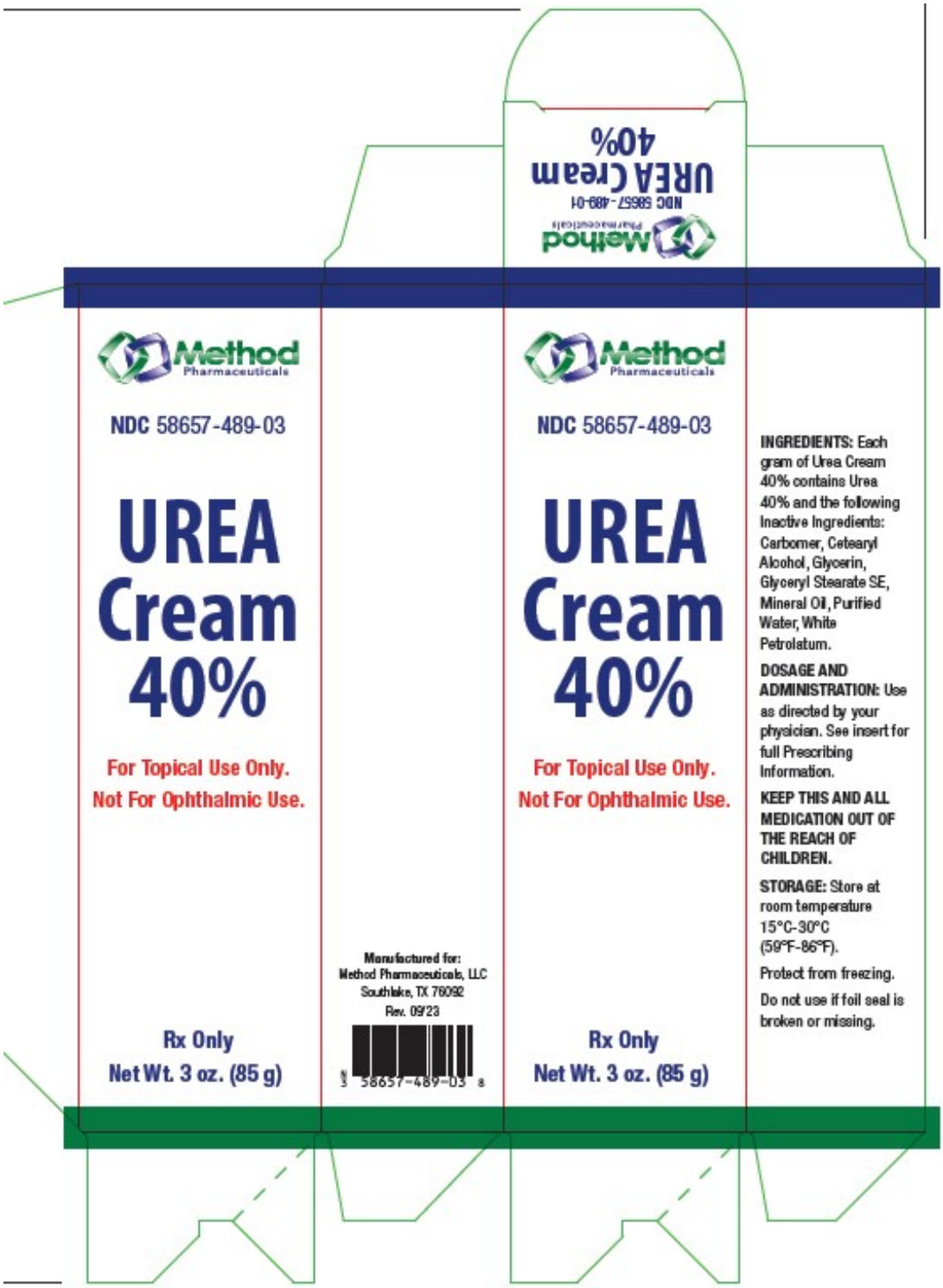
3x8mm




# UREA CREAM 40 PERCENT

urea cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:58657-489 |
| **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:58657-489-01 | 28.35 g in 1 BOTTLE; Type 0: Not a Combination Product | 10/31/2023 | |
| **2** | NDC:58657-489-03 | 85 g in 1 BOTTLE; Type 0: Not a Combination Product | 10/31/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/31/2023 | |

## Labeler - Method Pharmaceuticals, LLC (060216698)

Revised: 10/2023 Method Pharmaceuticals, LLC