UREA - urea cream
Trinity 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 Cream 39%
Rx Only

For external use only. Not for ophthalmic use.

Description
Urea Cream 39% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of Urea Cream 39% contains 39% urea as an active ingredient, and the following inactive ingredients: Water, Propylene Glycol, Glycerin, Stearate, Mineral Oil, Cetyl Alcohol, Carbomer, Petrolatum, Xanthan Gum and Sodium Hydroxide.

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

\[
\begin{align*}
\text{NH}_2 & \\
\text{C} & = \text{O} \\
\text{NH}_2
\end{align*}
\]

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 Cream 39% 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 Cream 39% 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 Cream 39% 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 39% Cream 8 oz. (226.8g): NDC 54295-311-18

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.

Marketed by:
Trinity Pharma LLC
2255 Glades Road
Suite 324A
Boca Raton, FL 33431
TrinityPharmaLLC.com
**INGREDIENTS:** Each gram of Urea Cream 39% contains Urea 39% and the following inactive ingredients: Water, Propylene Glycol, Glyceryl Stearate, Mineral Oil, Cetyl Alcohol, Carborner, Petrolatum, Xanthan Gum and Sodium Hydroxide.

**Product Information**

**Product Type:** HUMAN PRESCRIPTION DRUG

**Item Code (Source):** NDC:54295-311

**Route of Administration:** TOPICAL

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

Protect from freezing.

Keep bottle tightly closed.

**Rx Only**

For topical use only

Not for ophthalmic use

**Marketed by:**

Trinity Pharma LLC
2255 Glades Road
Suite 324A
Boca Raton, FL 33431

TrinityPharmaLLC.com

Rev. 2  8/2014

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

**Urea Cream 39%**

8 oz. (226.8g)

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**Active Ingredient/Active Moiety**

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)</td>
<td>UREA</td>
<td>39 g in 100 g</td>
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## Inactive Ingredients

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<td>WATER (UNII: 059QF0KO0R)</td>
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<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<tr>
<td>GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)</td>
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<tr>
<td>MINERAL OIL (UNII: T5L8T28FGP)</td>
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<tr>
<td>CETYL ALCOHOL (UNII: 936JST6JCN)</td>
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<tr>
<td>CARBOemer HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSsLINKED) (UNII: F68VH75CJC)</td>
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<tr>
<td>PETROLATUM (UNII: 4T6H12BN9U)</td>
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<tr>
<td>XANTHAN GUM (UNII: TTV12P4NEE)</td>
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<td>SODIUM HYdroXIDE (UNII: 55X04QC32I)</td>
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## Product Characteristics

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## Packaging

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<td>1 in 1 CARTON</td>
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<td>227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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## Marketing Information

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### Labeler

Trinity Pharmaceuticals, LLC (078671698)

Revised: 12/2019