

**UREA- urea cream**  
**Cintex Services, 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**

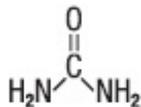
**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**DESCRIPTION:**

This product is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin.

Each gram contains 390 mg of urea in a vehicle consisting of: carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, purified water, sodium hydroxide and xanthan gum.

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:**

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: KEEP OUT OF REACH OF CHILDREN.**

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

**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:**

Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed.

#### **STORAGE:**

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

**NOTICE:** Protect from freezing and excessive heat. Keep container tightly closed.

#### **HOW SUPPLIED:**

8 oz. (227 g) bottles, **NDC** 24470-938-08

**To report** a serious adverse event or obtain product information, call 1-855-899-4237.

#### **Manufactured for:**

Cintex Services, LLC

9330 LBJ Freeway, Suite 900

Dallas, TX 75243

2300393 [00] Rev. 12/2023

<b>NDC 24470-938-08</b>	<b>Rx Only</b>	<b>DESCRIPTION:</b> This product is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin.
<b>Urea Cream</b>		Each gram contains 390 mg of urea in a vehicle consisting of: carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, purified water, sodium hydroxide and xanthan gum.
<b>39%</b>		<b>INDICATIONS:</b> 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.
<b>Net Wt. 8 oz. (227 g)</b>		<b>CONTRAINDICATIONS:</b> This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.
		<b>DOSAGE AND ADMINISTRATION:</b> Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed.
		See package insert for full prescribing information.
		<b>WARNING: KEEP OUT OF REACH OF CHILDREN.</b>
		<b>PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.</b> Avoid contact with eyes, lips and mucous membranes.
		<b>STORAGE:</b> Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 86°F). Protect from freezing and excessive heat.
		To report a serious adverse event or obtain product information, call 1-855-899-4237.
		<b>Manufactured for:</b> Cintex Services, LLC 9330 LBJ Freeway, Suite 900 Dallas, TX 75243 2300392 [00] Rev. 12/2023
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## UREA

urea cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:24470-938
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	390 mg in 1 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24470-938-08	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/23/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other		01/23/2024	
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**Labeler** - Cintex Services, LLC (078304114)

Revised: 1/2024

Cintex Services, LLC