

**UREA- urea cream**  
**Exact-Rx, Inc.**

*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.*

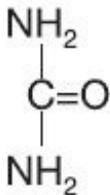
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(in a cream base)

**Rx only**

**For external use only. Not for ophthalmic use.**  
**Keep away from eyes, lips and mucous membranes.**

**DESCRIPTION: UREA CREAM 45%** is a keratolytic emollient, which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram contains 45% Urea in a cream base of: camphor, edetate disodium, alcohol, eucalyptus oil, hydroxyethyl cellulose, menthol, purified water, titanium dioxide, sodium hydroxide.

**CHEMISTRY:** 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. Urea also hydrates and gently dissolves the intercellular matrix of the nail plate, which can result in the softening and eventual removal of devitalized nail plate tissue.

**PHARMACOKINETICS:** The mechanism of action of topically applied Urea is not yet known.

**INDICATIONS AND USES:** Urea 45% Cream is indicated for use in the topical treatment 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, keratoderma, corns and calluses, as well as damaged devitalized and ingrown nails.

**CONTRAINDICATIONS:** Known hypersensitivity to any of the listed ingredients.

**WARNINGS:** For external use only. Avoid contact with eyes, lips or mucous membranes. If swallowed seek medical attention or contact a Poison Control Center immediately.

**PRECAUTIONS:** Use this medication only as directed by a physician. It should not be used to treat and condition other than that for which it was prescribed. If redness or irritation occurs, discontinue use. After applying this medication, wash hands and

unaffected areas thoroughly. **KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.**

**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 45% 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 45% is administered to a nursing woman.

**ADVERSE REACTIONS:**Transient stinging, burning itching or irritation may occur and normally disappear on discontinuing medication.

**Call your doctor for medical advice about side effects.**

**DOSAGE AND ADMINISTRATION:**Apply Urea Cream 45% to damaged nail tissue or affected skin area(s) twice a day or as directed by a physician.

**HOW SUPPLIED:**Urea Cream 45% is supplied in 9 oz. (255 g) tubes, NDC 42808-0202-09.

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). See USP Controlled Room Temperature. Protect from freezing.

**PRINCIPAL DISPLAY PANEL**

For External Use Only

Urea  
CREAM

45%

For External Use Only

NDC 42808-0202-09

Rx Only

Urea

In a vehicle containing  
camphor, eucalyptus oil  
and menthol

45%

CREAM

**FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC  
USE. KEEP AWAY FROM  
EYES, LIPS AND MUCOUS  
MEMBRANES**

Urea Cream 45% is indicated  
for the treatment of  
hyperkeratotic conditions  
such as dry, rough skin,  
dermatitis, psoriasis,  
xerosis, ichthyologist,  
eczema, keratosis,  
keratoderma, corns and  
calluses, as well as  
damaged, devitalized and  
ingrown nails.

**DIRECTIONS:** Apply cream  
to affected area(s). Rub in  
until cream is completely  
absorbed. Use only as  
directed by a physician.  
**See package insert for full  
prescribing information.**

**CAUTION:** If redness or  
irritation occurs,  
discontinue use.

NDC 42808-0202-09

Rx Only

Urea

In a vehicle containing  
camphor, eucalyptus oil  
and menthol

45%

CREAM

Each gram contains  
45% urea, camphor,  
carbomer, cetyl alcohol,  
disodium EDTA, euca-  
lyptus oil, glycerin,  
glyceryl stearate SE,  
menthol, mineral oil,  
PEG-100 stearate, puri-  
fied water, stearyl alco-  
hol, triacetin, white  
petrolatum.

**KEEP OUT OF REACH  
OF CHILDREN.** In case  
of accidental ingestion  
contact a poison control  
center immediately. Keep  
container tightly closed.

Store at 25°C (77°F);  
excursion permitted to  
15 to 30°C (59 to 86°F).  
See USP Controlled  
Room Temperature.  
Protect from freezing.

00-020209-101-03

342808202096

Manufactured in the U.S.A. for  
Exact-Rx, Inc.  
Melville, NY 11747

Exact-Rx

Net Wt. 9 oz (255g)

Exact-Rx

Net Wt. 9 oz (255g)



urea cream

**Product Information**

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:42808-202 |
| <b>Route of Administration</b> | TOPICAL                 |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>                           | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W) | UREA                     | 450 mg in 1 g   |

**Inactive Ingredients**

| <b>Ingredient Name</b>                  | <b>Strength</b> |
|---|-----------------|
| WATER (UNII: 059QF0KO0R)                |                 |
| WHITE PETROLATUM (UNII: B6E5W8RQJ4)     |                 |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)  |                 |
| EDETATE DISODIUM (UNII: 7FLD91C86K)     |                 |
| ALCOHOL (UNII: 3K9958V90M)              |                 |
| EUCALYPTUS OIL (UNII: 2R04ONI662)       |                 |
| GLYCERIN (UNII: PDC6A3C0OX)             |                 |
| MENTHOL (UNII: L7T10EIP3A)              |                 |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) |                 |
| PEG-100 STEARATE (UNII: YD01N1999R)     |                 |
| MINERAL OIL (UNII: T5L8T28FGP)          |                 |
| CETYL ALCOHOL (UNII: 936JST6JCN)        |                 |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y)      |                 |

**Packaging**

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:42808-202-09 | 1 in 1 CARTON                                      | 08/01/2011           |                    |
| 1 |                  | 255 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| unapproved drug<br>other  |   | 08/01/2011                  |                           |

**Labeler** - Exact-Rx, Inc. (137953498)

