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.

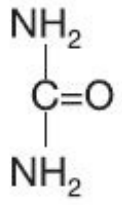
(in a cream base)

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 Centter 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.

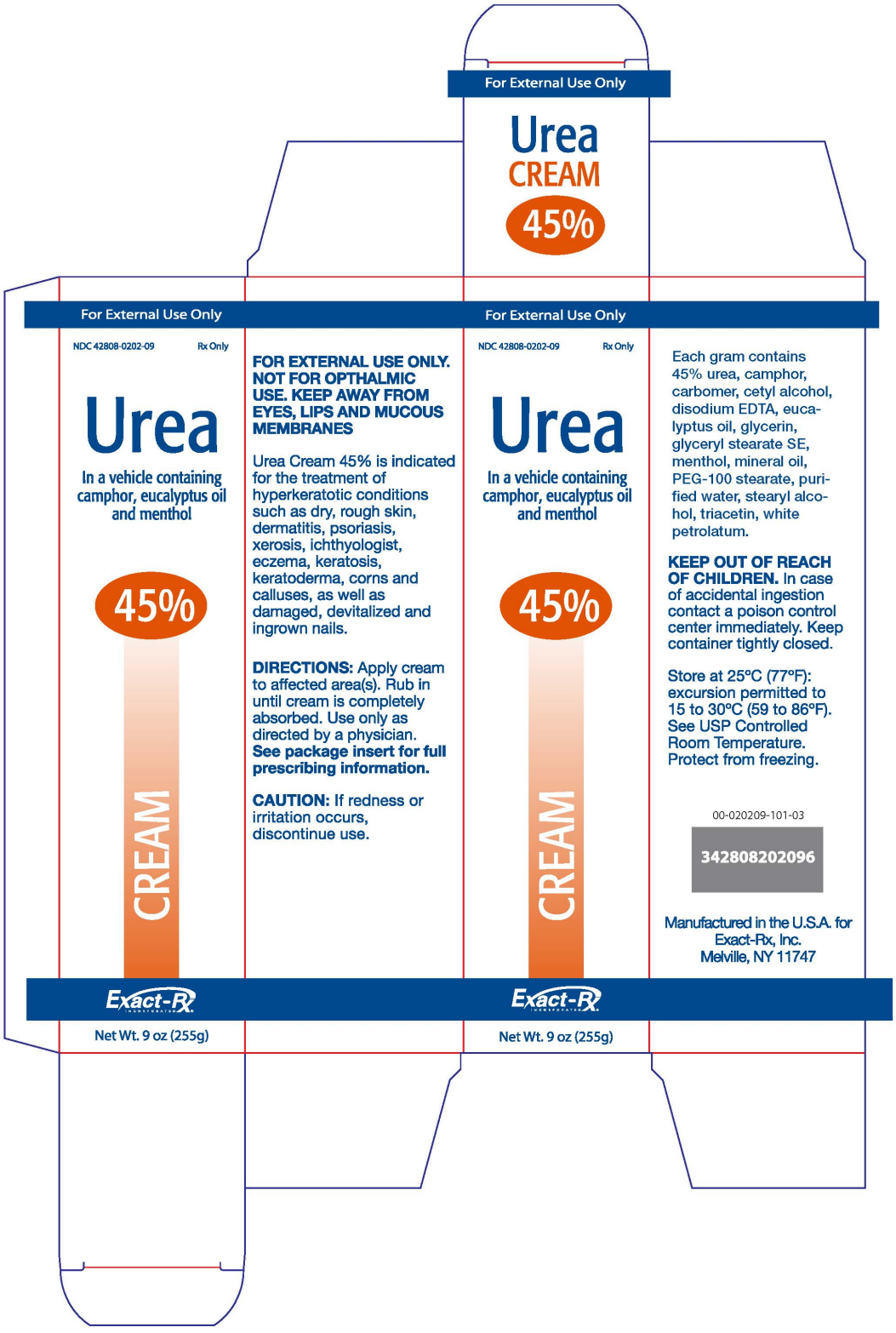
Call your doctor for medical advice about side effects.

DOSAGE AND ADMINSTRATION: 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
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 OPTHALMIC 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, eucalyptus oil, glycerin, glyceryl stearate SE, menthol, mineral oil, PEG-100 stearate, purified water, stearyl alcohol, 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

urea cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42808-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	450 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2011	

Labeler - Exact-Rx, Inc. (137953498)