CEM-UREA - urea solution
PruGen, 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.

CEM-UREA TM PRE-FILLED APPLICTOR REV.1.0

CEM-UreaTM (45% Urea) is a keratolytic emollient, which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of CEM-UreaTM (45% Urea) contains 45% Urea, camphor, edetate disodium, eucalyptus oil, hydroxyethyl cellulose, menthol, methyl paraben, propylene glycol and purified water.
Urea is a diamide of carbonic acid with the following chemical structure:

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 debridement of the nail plate.

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

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.

Known hypersensitivity to any of the listed ingredients.

For external use only. Avoid contact with eyes, lips or mucous membranes.

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.

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, CEM-UreaTM (45% Urea) should be given to a pregnant woman only if clearly needed.

It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when CEM-UreaTM (45% Urea) is administered to a nursing woman.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Transient stinging, burning, itching or irritation may occur and normally disappear
on discontinuing the medication.

DIRECTIONS FOR NAILS: Apply CEM-UreaTM (45% Urea) to diseased or damaged nail tissue twice per day, or as directed by a physician.

DIRECTIONS FOR SKIN: Apply CEM-UreaTM (45% Urea) to affected area(s) twice per day, or as directed by a physician.

CEM-UreaTM (45% Urea) 20 mL tube, NDC 42546-100-20

Store at controlled room temperature 15°-30° C (59°-86° F).
Protect from freezing.

NDC 42546-100-20

CEM-Urea Pre-Filled Applicator 45% urea

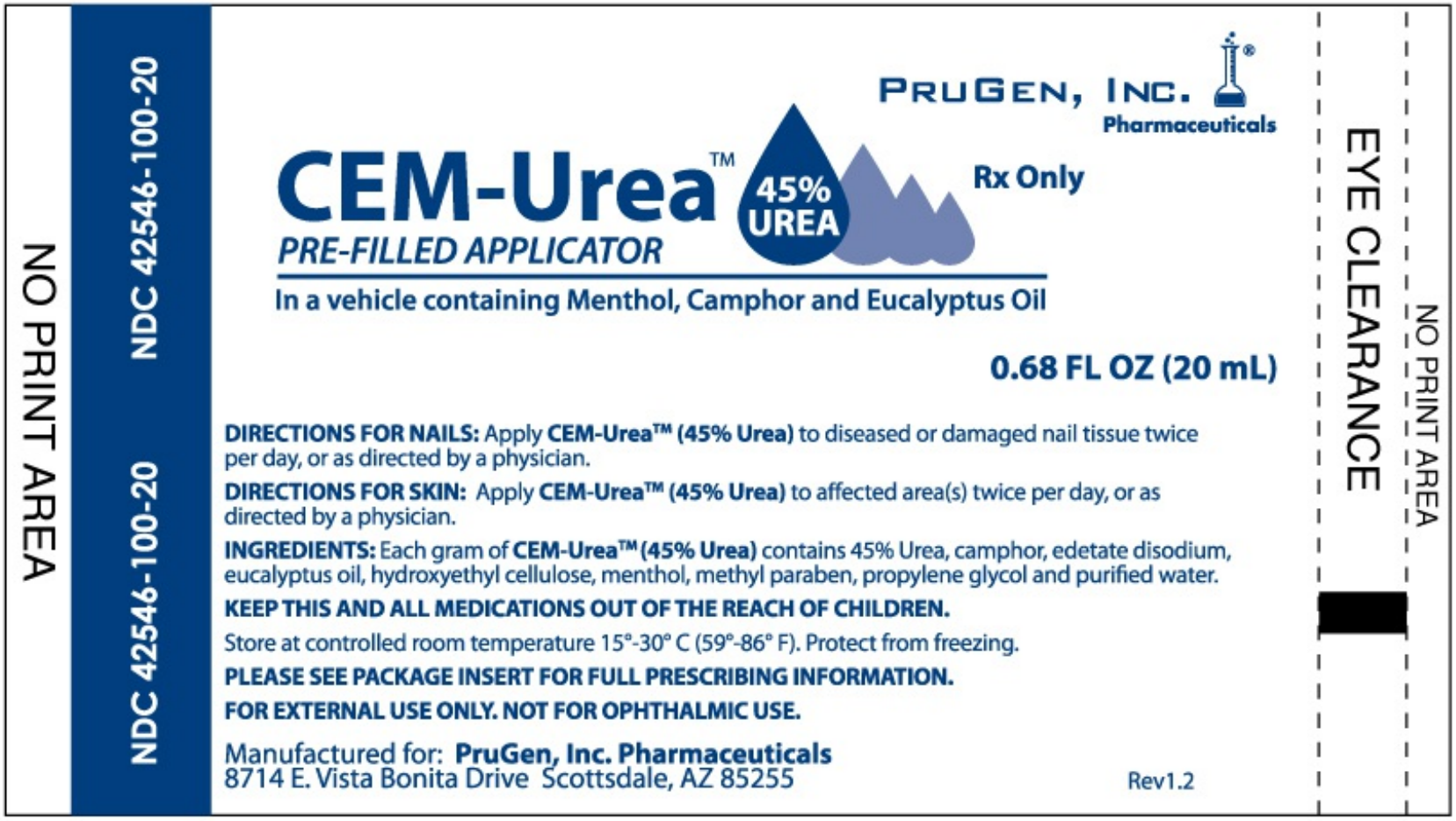
In a vehicle containing Menthol, Camphor, and Eucalyptus Oil

Rx only

0.68 FL OZ (20 mL)

PruGen, Inc. Pharmaceuticals

CEM-UREA


NO PRINT AREA
NDC 42546-100-20
NDC 42546-100-20
PRUGEN, INC.
Pharmaceuticals
CEM-Urea™
45% UREA
Rx Only
PRE-FILLED APPLICATOR
In a vehicle containing Menthol, Camphor and Eucalyptus Oil
0.68 FL OZ (20 mL)
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INGREDIENTS: Each gram of CEM-Urea™ (45% Urea) contains 45% Urea, camphor, edetate disodium, eucalyptus oil, hydroxyethyl cellulose, menthol, methyl paraben, propylene glycol and purified water.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Store at controlled room temperature 15°-30° C (59°-86° F). Protect from freezing.
PLEASE SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.
Manufactured for: PruGen, Inc. Pharmaceuticals
8714 E. Vista Bonita Drive Scottsdale, AZ 85255
Rev1.2
EYE CLEARANCE
NO PRINT AREA

urea solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42546-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	.45 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
HYDROXYETHYL CELLULOSE (3000 CPS AT 1%) (UNII: 7Q6P4JN1QT)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
MENTHOL (UNII: L7T10EIP3A)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42546-100-20	1 in 1 BOX		
1		20 mL in 1 APPLICATOR		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other		07/01/2011	

Labeler - PruGen, Inc. (929922750)

Revised: 8/2011 PruGen, Inc.