URE-39- urea cream
SOLUTECH 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.

URE-39
(Urea 39% Cream)

Rx only

For external use only.

Not for ophthalmic use.

URE-39 Description

URE-39 Cream is a potent keratolytic emollient which is a gentle, yet potent, tissue softener for skin and/or nails.

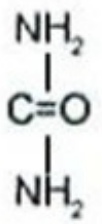
Each gram of **URE-39** Cream contains:

ACTIVE: 39% Urea in a cream base of:

INACTIVES: Deionized Water, Carthamus Tinctorius (Safflower) Seed Oil, Emulsifying Wax, Glycerine, Propylene Glycol, Glyceryl Stearate, PEG 100 Stearate, Cetyl Alcohol, Dimethicone, C12/15 Alkyl Benzoate, Anthemis Nobilis (Chamomile) Flower Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aloe Barbadensis Leaf, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, and Isobutylparaben.

CHEMISTRY

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



URE-39 - 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 debridement of the nail plate.

PHARMACOKINETICS

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

INDICATIONS AND USES

For debridement and promotion of normal healing of hyperkeratotic surface lesions, particularly where

healing is retarded by local infection, necrotic tissue, fibrinous or prurient 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, ingrown and devitalized nails.

Contraindications

URE-39 Cream is contraindicated in patients with known hypersensitivity to any of the listed ingredients.

Warnings

For external use only. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin.

Precautions

Stop use and ask a doctor if redness or irritation develops. After applying this medication, wash hands and unaffected areas thoroughly. If swallowed, get medical help or contact Poison Control Center right away. KEEP THIS AND ALL MEDICATION OUT OF THE 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 reproduction studies are not always predictive of human response, **URE-39** Cream should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

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 **URE-39** Cream is administered to a nursing woman.

Adverse Reactions

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

URE-39 - Dosage and Administration

Apply **URE-39** Cream to affected skin two to three times per day as needed or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail tissue two to three times per day or as directed by a physician. Best applied to affected areas immediately after showering and just before bedtime.

How is URE-39 Supplied

URE-39 (39% Urea Cream) is supplied in:

8oz (227gm) Jar NDC: 70350-2612-1

Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59° - 86°F). Protect from freezing. [See

USP Controlled Room Temperature.]

Manufactured for:
Solutech Pharmaceuticals LLC
Peoria, AZ 85345

Rx only

PRINCIPAL DISPLAY PANEL - 227 gm Jar Label

NDC 70350-2612-1

FOR TOPICAL USE ONLY

URE-39
UREA 39% CREAM

Smooth Easily Spreadable

Rx only

Solu**tech**
PHARMACEUTICALS

Net WT.
8OZ (227 gm)

NDC 70350-2612-1

FOR TOPICAL USE ONLY

URE-39

UREA 39% CREAM

Smooth Easily Spreadable

Rx only Solutech PHARMACEUTICALS Net WT. 8OZ (227 gm)

DRUG FACTS

Ingredient	Purpose
Urea 39%	Moisturizer

Ingredients: Deionized Water, Carthamus Tinctorius (Safflower) Seed Oil, Emulsifying Wax, Glycerine, Propylene Glycol, Glyceryl Stearate, PEG 100 Stearate, Cetyl Alcohol, Dimethicone, C12/15 Alkyl Benzoate, Anthemis Nobilis (Chamomile) Flower Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aloe Barbadensis Leaf, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben

Indications: Debrides rough patches and dead skin while moisturizing living tissue and rehydrating derma to a healthy appearance.

DRUG FACTS (cont.)

Directions: Apply up to 2 to 3 times per day as needed to dry skin areas. Best applied to affected areas immediately after showering and just before bedtime.

Warnings: Should signs of irritation develop, discontinue use. Not for ophthalmic use. Keep away from eyes, lips and mucous membranes. Do not use on open wounds, cracked, or bleeding skin. For external use only.

Keep out of reach of children
If swallowed, get medical help or contact a poison control center immediately.

MANUFACTURED FOR: Solutech PHARMACEUTICALS PEORIA, ARIZONA NDC 70350-2612-1

876510020441

URE-39

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70350-2612
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
TEA TREE OIL (UNII: VIF565UC2G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70350-2612-1	227 g in 1 JAR; Type 0: Not a Combination Product	09/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/01/2017	

Labeler - SOLUTECH PHARMACEUTICALS LLC (080040396)

Revised: 3/2018 SOLUTECH PHARMACEUTICALS LLC