URE-K- 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-K 50%
(Urea 50% in a cream base)

Rx only

For external use only.
Not for ophthalmic use.

URE-K 50% Description

URE-K 50% cream is a potent keratolytic emollient which is a gentle, yet potent, tissue softener for skin and/or nails.

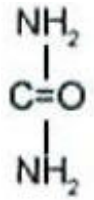
Each gram of **URE-K 50%** cream contains:

ACTIVE: 50% Urea in a cream base of:

INACTIVES: Mineral Oil, Stearic Acid, Water, Glycerin, Polysorbate 20, Sepigel 305, Phenoxyethanol, Acrylate Copolymer and Vitamin E

CHEMISTRY

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



URE-K 50% - 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 USAGE

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-K 50% 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

After applying this medication, wash hands and unaffected areas thoroughly. Stop use and ask a doctor if redness or irritation develops. 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-K 50%** 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-K 50%** 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-K 50% - Dosage and Administration

Apply **URE-K 50%** cream to affected skin twice per day or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail tissue twice per day or as directed by a physician.

How is URE-K 50% Supplied

URE-K 50% cream (50% urea) is supplied in:

142g (5 oz) tube 70350-2600-5

Store at 25°C (77°F); excursion 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 - 142 gm Tube Label

NDC 70350-2600-5

FOR TOPICAL USE ONLY

URE-K 50%

50% UREA IN A CREAM BASE

Smooth
Easily Spreadable

Rx only

Solutech
PHARMACEUTICALS

Net WT. 5OZ (142 gm)

URE-K

urea cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70350-2600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	500 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70350-2600-5	142 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/01/2016	

Labeler - Solutech Pharmaceuticals LLC (080040396)

Revised: 10/2017 Solutech Pharmaceuticals LLC