UREA CREAM 41%- urea cream
Laser 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.

Urea Cream 41%

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Rx Only For external use only. Not for ophthalmic use.

Description

Urea 41% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of Urea 41% contains 41% urea as an active ingredient, and the following inactive ingredients: Ceteareth-6, Ceteareth-25, Cetyl Alcohol, Mineral Oil, Propylene Glycol, Purified Water, Sodium Hydroxide, Stearyl Alcohol, Xanthan Gum.

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

Clinical Pharmacology

Urea gently dissolves the intracellular matrix which results in loosening of the horny layer of the skin and shedding of scaly skin at regular intervals, thereby softening hyperkeratotic areas of the skin.

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 purulent debris or eshar. Urea is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis pilaris, keratosis palmaris, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.

Contraindications

Known hypersensitivity to any of the listed ingredients.

Warnings

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

Precautions

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 and consult a physician.

PREGNANACY: 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 41% 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 41% is administered to a nursing woman.

Adverse Reactions

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

Dosage and Administration

Apply Urea 41% to affected skin twice per day, or as directed by your physician. Rub in until completely absorbed.

Apply to diseased or damaged nail(s) twice per day, or as directed by a physician.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made**

as to generic status or bioequivalency. Each person recommending a prescription substitution using this product shall make such recommendations based on each person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical information provided herein.

How Supplied

Urea 41% Cream 8 oz.(227 g): NDC 16477-341-08

Store at room temperature 15°C - 30°C (59°F - 86°F). Protect from freezing. Keep bottle tightly closed.

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

Marketed by:
Laser Pharmaceuticals, LLC
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1-844-302-5227

UREA CREAM 41%

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16477-341
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	410 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETEARETH-25 (UNII: 8FA93U5T67)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETEARETH-6 (UNII: 2RJS3559D3)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16477-341-08	1 in 1 CARTON	05/04/2018	
1		227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/04/2018	

Labeler - Laser Pharmaceuticals, LLC (614417132)