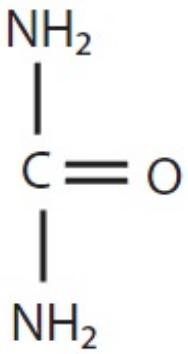
UREA- urea emulsion
ACELLA PHARMACEUTICALS

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.

50% UREA EMULSION

DESCRIPTION: Each gram of 50% Urea Emulsion contains 50% urea in a formulation consisting of: caprylic/capric triglyceride, cetyl alcohol, disodium EDTA, glycerin, hydroxyethyl cellulose, lactic acid, linoleic acid, PEG-6, polysorbate 60, propylene glycol, sorbitan stearate, titanium dioxide, triethanolamine, purified water, vitamin E, xanthan gum and zinc undecylenate.

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.

PHARMACOKINETICS: The mechanism of action of the 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 eschar. 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.

CONTRAINDICATIONS: Known hypersensitivity to any of the listed ingredients.

WARNINGS: For external 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.

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, 50% Urea Emulsion 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 50% Urea Emulsion is administered to a nursing woman

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

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

DOSAGE AND ADMINISTRATION: Apply 50% Urea Emulsion to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed.

HOW SUPPLIED: 50% Urea Emulsion is supplied in a 10 oz. tube (NDC 42192-101-10). Store at controlled room temperature, 15° - 30° (59° - 86°F). Protect from freezing.

All prescription substitutions 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. Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, incipients, inactive ingredients and chemical formulation information provided herein.

MANUFACTURED FOR: Acella Pharmaceuticals, LLC
9005 Westside Parkway
Alpharetta, GA 30009
1-800-541-4802

How to properly use

50% Urea

Emulsion

In a zinc undecylenate and lactic acid vehicle

Easy steps to treat dry skin conditions including psoriasis, xerosis, ichthyosis, keratosis pilaris, keratosis palmaris,

keratoderma, dermatitis, pruritus, eczema, corns and calluses.

For skin:

1. Apply 50% Urea Emulsion to affected skin twice per day, or as directed by a physician.

2. Rub in until completely absorbed (for best results apply to moistened skin).

NDC 42192-101-10

50% Urea
Emulsion
In a zinc undecylenate and lactic acid vehicle

Rx Only
Net Weight 10 oz
For Topical Use Only

Indications: For use on rough dry skin conditions. See carton or package insert for instructions.

USE ONLY AS DIRECTED BY A PHYSICIAN.

Ingredients: Each gram of 50% Urea Emulsion contains 50% urea in a formulation consisting of caprylic or capric triglyceride, cetyl alcohol, disodium EDTA, glycerin, hydroxyethyl cellulose, lactic acid, linoleic acid, PEG-6, polysorbate 60, propylene glycol, sorbitan stearate, titanium dioxide, triethanolamine, purified water, vitamin E, xanthan gum and zinc undecylenate.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

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

For lot number and expiration date, see crimp of tube.

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UREA
urea emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	50 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TRICAPRIN (UNII: O1PB8EU98M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
LACTIC ACID (UNII: 33X04XA5AT)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ZINC UNDECYLENATE (UNII: 388VZ25DUR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-101-10	283.5 g in 1 TUBE; Type 0: Not a Combination Product	06/29/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/29/2009	

Labeler - ACELLA PHARMACEUTICALS (825380939)

Revised: 3/2018 ACELLA PHARMACEUTICALS