

UREA HYDRATING TOPICAL- urea aerosol, foam

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](#).

UREA 35% HYDRATING TOPICAL FOAM (urea in a water and lipid based foam containing lactic acid, 35%) Rx Only

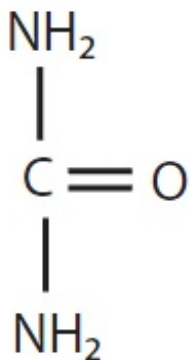
DESCRIPTION

Urea 35% Hydrating Topical Foam is a keratolytic emollient in a water and lipid based foam containing lactic acid which is a gentle, but potent, tissue softener for skin and nails.

Each gram of Urea 35% Hydrating Topical Foam contains Urea 35% as the active ingredient, and the following inactive ingredients: dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and in propellants butane and propane.

CHEMICAL STRUCTURE

Urea has the following chemical structure:



CLINICAL PHARMACOLOGY

Topically applied urea dissolves the intercellular matrix of the skin which results in enhanced shedding of scaly, dry skin and thus a softening of the hyperkeratotic areas of the skin.

Urea topically applied to the nail plate has a similar effect on the intercellular matrix of the nail plate.

PHARMACOKINETICS

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

INDICATIONS AND USAGE

For enzymatic debridement and promotion of normal healing of surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris,

or eschar. Topically applied urea is useful for the treatment of hyperkeratotic conditions such as dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, and dry, rough skin, as well as corns and calluses and damaged, ingrown and devitalized nails.

CONTRAINDICATIONS

Known hypersensitivity to any of the listed ingredients.

WARNINGS

Urea 35% Hydrating Topical Foam is for external use only. It is not for ophthalmic, oral, anal or intravaginal use. Contact with eyes, lips, and all mucous membranes should be avoided. Urea 35% Hydrating Topical Foam should not be used by persons who have a known hypersensitivity to urea or any of the other listed ingredients.

PRECAUTIONS

Urea 35% Hydrating Topical Foam should be used only as directed by a physician and should not be used to treat any condition other than that for which it is prescribed. If redness

or irritation occurs, discontinue use and consult with a prescribing physician.

Pregnancy (Category B) – Animal reproduction studies have not been performed with topically applied urea and it is not known whether Urea 35% Hydrating Topical Foam can cause fetal harm when administered to a pregnant woman. Nevertheless, Urea 35% Hydrating Topical Foam should be used by a pregnant woman only if necessary.

Nursing Mothers – It is not known whether topically applied urea is excreted in human milk. Due to the fact that many drugs are excreted in human milk, caution should be exercised by physicians when administering Urea 35% Hydrating Topical Foam to nursing mothers.

ADVERSE REACTIONS

Transient stinging, burning, itching or irritation is possible.

DOSAGE AND ADMINISTRATION

Unless otherwise directed by a prescribing physician, Urea 35% Hydrating Topical Foam should be applied to affected area twice a day. Urea 35% Hydrating Topical Foam should be rubbed into the skin until it is completely absorbed.

HOW SUPPLIED

Urea 35% Hydrating Topical Foam is supplied in a 150 gram or 5.3 ounce aerosolized canister bearing the NDC Number 42192-115-15.

Enter section text here

NDC 42192-115-15

Urea 35% Hydrating Topical Foam

(35% Urea in a vehicle containing lactic acid)

Rx Only

Net Wt. 5.3 oz. (150 g)

Acella
PHARMACEUTICALS, LLC

Dosage and Administration: Clean and dry affected skin. Then apply Urea 35% Hydrating Topical Foam topically to cover affected skin twice per day, or as directed by a physician. Rub in until completely absorbed.

Shake vigorously before each application and invert can to administer.

Store at room temperature 59° - 77°F (15° - 25°C).

See prescribing information for additional details.

Ingredients: urea 35%, dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, triethylamine, and in propellants butane and propane.

Warning: Contents under pressure. Do not puncture or incinerate. Do not expose to temperatures over 120°F (48°C) even when empty. Keep out of reach of children.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802



Rev. 0410V2

NDC 42192-115-15

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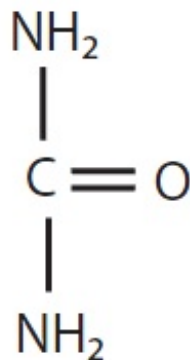
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Rev. 0410v2

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UREA HYDRATING TOPICAL

urea aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-115
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	35 g in 100 g

Inactive Ingredients				
Ingredient Name			Strength	
DIMETHICONE (UNII: 92RU3N3Y1O)				
ETHYLPARABEN (UNII: 14255EXE39)				
GLYCERIN (UNII: PDC6A3C0OX)				
LACTIC ACID (UNII: 33X04XA5AT)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TROLAMINE (UNII: 9O3K93S3TK)				
BUTANE (UNII: 6LV4FOR43R)				
PROPANE (UNII: T75W9911L6)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-115-15	150 g in 1 CANISTER; Type 0: Not a Combination Product	05/21/2010	11/30/2024
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			05/21/2010	11/30/2024

Labeler - Acella Pharmaceuticals (825380939)

Registrant - Acella Pharmaceuticals (825380939)

Establishment			
Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticlas		825380939	manufacture(42192-115)