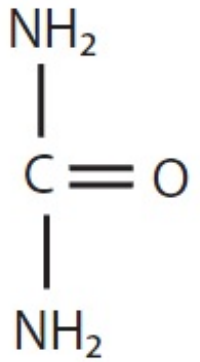
UREA HYDRATING TOPICAL- urea aerosol, foam
Acella Pharmaceuticals

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.

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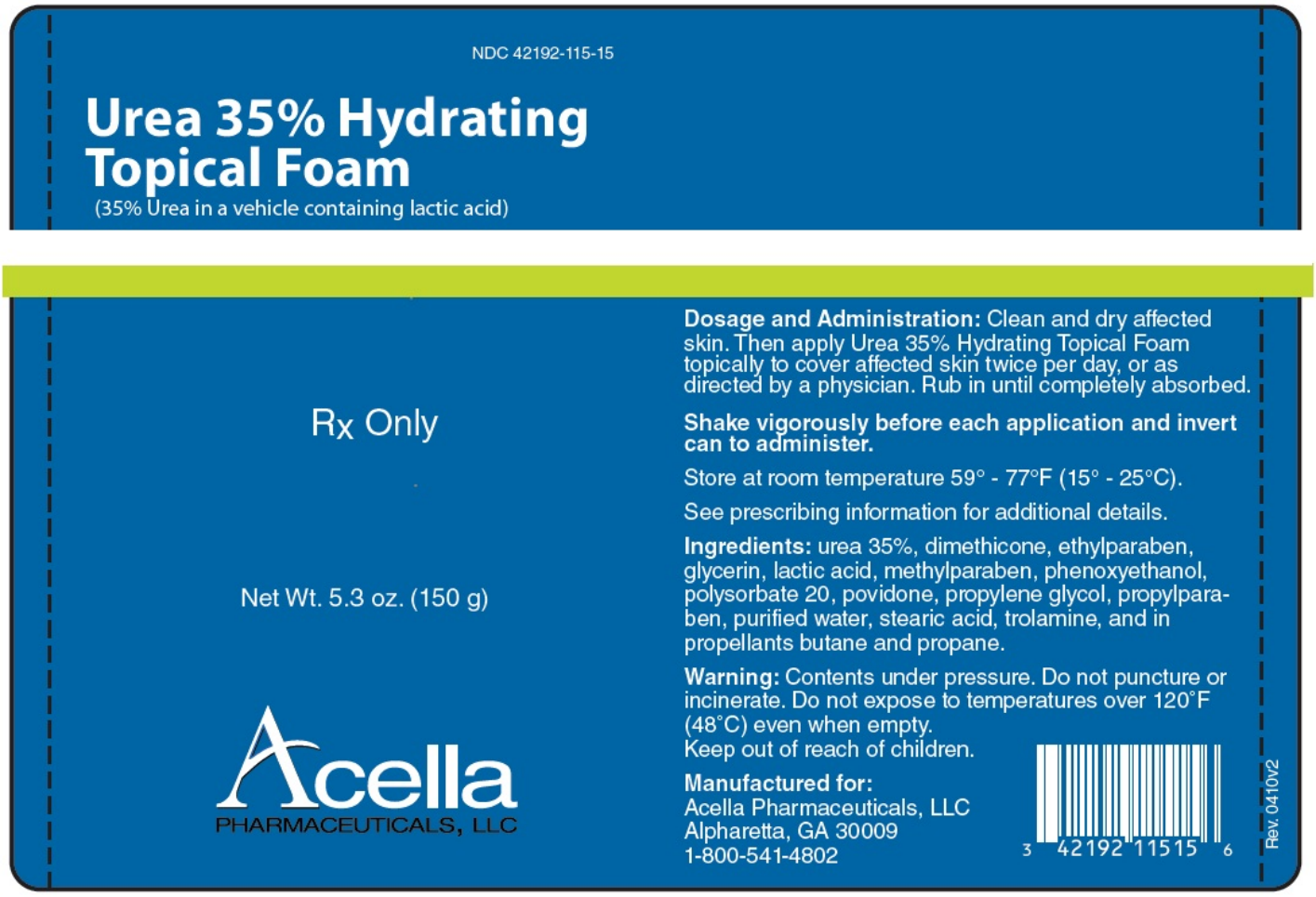

NDC 42192-115-15

Urea 35% Hydrating

Topical Foam

Rx Only

Net Wt. 5.3 oz. (150 g)

NDC 42192-115-15

Rx Only

Net Wt. 5.3 oz. (150 g)

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, trolamine, 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

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.

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See prescribing information for additional details.

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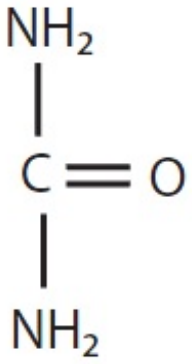
Rev. 0410v2



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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/21/2010	

Labeler - Acella Pharmaceuticals (825380939)

Registrant - Acella Pharmaceuticals (825380939)

Establishment

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

Revised: 1/2024 Acella Pharmaceuticals