Urea 35% Hydrating Topical Foam

(urea in a water and lipid based foam containing lactic acid, 35%)
Rx ONLY

ACTIVE INGREDIENTS: 35% Urea

INACTIVE INGREDIENTS: Carbomer, Dimethicone, Ethylparaben, Glycerin, Lactic Acid, Laureth-4, Methylparaben, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Propylparaben, Stearic Acid, Triethanolamine, Water. Propellant contains butane and propane.

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: butane, carbomer, dimethicone, ethylparaben, glycerin, lactic acid, laureth-4, methylparaben, phenoxyethanol, polysorbate 20, propane, propylene glycol, propylparaben, stearic acid, triethanolamine, water.

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.

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

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.

Shake vigorously before each application and invert can to administer.

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.

STORAGE

Store at 20° - 25°C (68 -77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature].

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 recommendation based on her professional opinion and knowledge, upon evaluating the active ingredients, inactive ingredients, excipients and other chemical information provided herein.

MANUFACTURED FOR

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