

HYDRO 40® Hydrating Topical Foam

(urea in a water and lipid based foam, 40%)

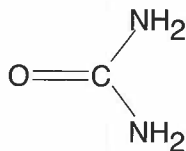
Rx Only

DESCRIPTION

HYDRO 40 is a keratolytic emollient in a water and lipid based foam which is a gentle, but potent, tissue softener for skin and nails. Each gram of HYDRO 40 contains Urea 40% as the active ingredient, and the following inactive ingredients: dimethicone, ethyl paraben, glycerine, methyl paraben, colloidal oatmeal, phenoxyethanol, polysorbate 20, polyvinylpyrrolidone, propyl paraben, propylene glycol, purified water, stearic acid, triethanolamine and in propellants butane, isobutane 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

HYDRO 40 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. HYDRO 40 should not be used by persons who have a known hypersensitivity to urea or any of the other listed ingredients.

PRECAUTIONS

HYDRO 40 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 prescribing physician.

Pregnancy (Category C) - Animal reproduction studies have not been performed with topically applied urea and it is not known whether HYDRO 40 can cause fetal harm when administered to a pregnant woman. Nevertheless, HYDRO 40 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 HYDRO 40 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, HYDRO 40 should be applied to affected area twice a day. HYDRO 40 should be rubbed into the skin until it is completely absorbed.



HOW SUPPLIED

HYDRO 40 is supplied in a 150 gram or 5.3 ounce aerosolized canister bearing the NDC Number 23710-040-15.

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

U.S. Patent Pending for HYDRO 40.

HYDRO 40 is manufactured for Quinnova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 660-6263, www.QUINNOVA.com.

Prescribing Information as of June 2007.



PI-HYDRO 40 150ML

HYDRO 40™ FOAM

(urea in a water and lipid based foam, 40%)

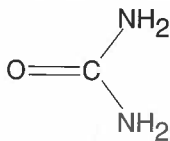
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DESCRIPTION

HYDRO 40 FOAM is a keratolytic emollient in a water and lipid based foam which is a gentle, but potent, tissue softener for skin and nails. Each gram of HYDRO 40 FOAM contains Urea 40% as the active ingredient, and the following inactive ingredients: dimethicone, ethyl paraben, glycerine, methyl paraben, colloidal oatmeal, phenoxyethanol, polysorbate 20, polyvinylpyrrolidone, propyl paraben, propylene glycol, purified water, stearic acid, triethanolamine and in propellants butane, isobutene 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

HYDRO 40 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. HYDRO 40 FOAM should not be used by persons who have a known hypersensitivity to urea or any of the other listed ingredients.

PRECAUTIONS

HYDRO 40 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 prescribing physician.

Pregnancy (Category C) - Animal reproduction studies have not been performed with topically applied urea and it is not known whether HYDRO 40 FOAM can cause fetal harm when administered to a pregnant woman. Nevertheless, HYDRO 40 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 HYDRO 40 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, HYDRO 40 FOAM should be applied to affected area twice a day. HYDRO 40 FOAM should be rubbed into the skin until it is completely absorbed.



HOW SUPPLIED

HYDRO 40 FOAM is supplied in a 70 gram or 2.5 ounce aerosolized canister bearing the NDC Number 23710-040-75.

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

U.S. Patent Pending for HYDRO 40 FOAM.

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Prescribing Information as of June 2007.



HYDRO 40™ FOAM

(urea in a water and lipid based foam, 40%)

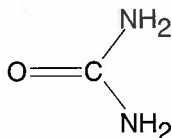
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PHARMACOKINETICS

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INDICATIONS AND USAGE

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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, HYDRO 40 FOAM should be applied to affected area twice a day. HYDRO 40 FOAM should be rubbed into the skin until it is completely absorbed.



HOW SUPPLIED

HYDRO 40 FOAM is supplied in a 22 gram or 0.79 ounce aerosolized canister bearing the NDC Number 23710-040-20.

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

U.S. Patent Pending for HYDRO 40 FOAM.

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Prescribing Information as of June 2007.

