

fougera®

How to properly use

UREA 50% EMULSION

In a zinc undecylenate
and lactic acid vehicle

Rx only

May help in treatment of dry skin conditions including psoriasis, xerosis, ichthyosis, keratosis pilaris, keratosis palmaris, keratoderma, dermatitis, pruritus, eczema, corns and calluses.

For skin:

1. Apply Urea 50% 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).
3. Avoid contact with eyes, lips, and mucous membranes. Wash hands after application. See full prescribing information on reverse side.

UREA 50% EMULSION

In a zinc undecylenate and lactic acid vehicle

For external use only.
Not for ophthalmic use.

DESCRIPTION: Each gram of Urea 50% Emulsion contains 50% urea in a formulation consisting of: caprylic/capric triglyceride, cetyl alcohol, disodium EDTA, glycerin, hydroxyethylcellulose, 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 topically applied urea is not yet known.

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

HOW SUPPLIED: Urea 50% Emulsion is supplied as a: 10 oz tube, NDC 0168-0646-10

Store at room temperature
15°-30° C (59°-86° F).

Protect from freezing.

Manufactured for:

E. FOUGERA & CO.
A division of Nycomed US Inc.
Melville, New York 11747

Manufactured by:
Pegasus Laboratories, Inc.
Pensacola, FL 32514