

INSTRUCTIONS FOR USE

fougera[®]

UREA NAIL GEL 50%

In a vehicle containing lactic acid and zinc

R only

Steps to gently thin and soften diseased, devitalized and ingrown nails, as well as thick, rough or dry skin seen in corns and calluses.

For nail(s):

1. Apply Urea Nail Gel 50% to affected nail(s) twice per day, or as directed by a physician.
2. Let dry uncovered or apply and cover with adhesive bandage or gauze secured with adhesive tape.

For skin:

1. Apply Urea Nail Gel 50% to affected skin twice per day, or as directed by a physician.

Urea Nail Gel 50%

In a vehicle containing
lactic acid and zinc

For external use only. Not for ophthalmic use.

DESCRIPTION: Urea Nail Gel 50% is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of Urea Nail Gel 50% contains 50% urea and the following inactive ingredients: disodium EDTA, hydroxyethylcellulose, lactic acid, PEG-6, propylene glycol, purified water, triethanolamine, xanthan gum and zinc pyrithione.

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. Urea also hydrates and gently dissolves the intercellular matrix of the nail plate, which can result in the softening and eventual debridement of the nail plate.

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, as well as damaged, ingrown and devitalized nails.

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 reproductive studies are not always predictive of human response, Urea Nail Gel 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 Nail Gel 50% 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 Nail Gel 50% to diseased or damaged nail(s) twice per day, or as directed by a physician. Let dry uncovered or apply and cover with adhesive bandage or gauze secured with adhesive tape. Apply to affected skin twice per day, or as directed by a physician.

HOW SUPPLIED: Urea Nail Gel 50% is supplied as follows:

18 mL (0.6 oz) bottle, NDC 0168-0490-18

Store at 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
Pensacola, FL 32514