

QUINNOSTIK

(nail stick 50% urea in a vehicle containing Lactic Acid and Zinc)

Rx Only

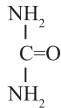
For external use only. Not for ophthalmic use.

DESCRIPTION

QUINNOSTIK (50% Urea) is a keratolytic solution, which is a gentle, yet potent, tissue softener for nails. Each mL of QUINNOSTIK contains 50% Urea, Edetate Disodium, Hydroxyethylcellulose, Lactic Acid, Propylene Glycol, Purified Water, Trolamine, Xanthan Gum and Zinc Pyrion.

CHEMICAL STRUCTURE

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 USAGE

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, keratoderma, corns and calluses, as well as damaged, devitalized, and ingrown 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, QUINNOSTIK should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when QUINNOSTIK 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 is possible and normally disappear on discontinuing the use of QUINNOSTIK.

DOSAGE AND ADMINISTRATION

Apply QUINNOSTIK to diseased or damaged nail tissue twice per day, or as directed by a physician.

HOW SUPPLIED

QUINNOSTIK is supplied as part of the RINNOVI Nail System, which bears the NDC Number 23710-050-02 and contains the following components:

- 6 QUINNOSTIKS (2.4mL)
- 1 Cleanser spray (30mL)
- 1 Protectant spray (30mL)

Store at controlled room temperature 15°-30° C (59°-86° F) Protect from freezing.

U.S. Patent Pending for the RINNOVI Nail System.

QUINNOSTIK and the RINNOVI Nail System are manufactured for Quinnova Pharmaceuticals, Inc., Newtown, PA 18940, (877) 660-6263, www.QUINNOVA.com.

Prescribing Information as of June 2007

