

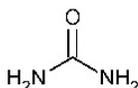


Vanamide™
urea cream, 40%

For topical use only. Not for ophthalmic use.

DESCRIPTION: Vanamide™ is a keratolytic, emollient cream which is a potent tissue softener for skin or nails. Each gram of Vanamide contains urea (40%), purified water, light mineral oil, glyceryl stearate, cetyl alcohol, petrolatum, gluconolactone, triethanolamine, xanthan gum and propylene glycol.

CHEMICAL STRUCTURE:



CLINICAL PHARMACOLOGY: Urea dissolves the intercellular matrix and thereby softens hyperkeratotic areas by enhancing the shedding of scales.

Pharmacokinetics: The mechanism of action of topically applied urea is not yet known.

INDICATIONS AND USES: 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.

CONTRAINDICATIONS: Known hypersensitivity to any of the listed ingredients.

WARNINGS: For external use only. Avoid contact with eyes.

PRECAUTIONS: If redness or irritation occurs, discontinue use. Wash excess cream from unaffected skin areas thoroughly, including hands, after contact. **KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

ADVERSE REACTIONS: The following local adverse reactions may occur: transient stinging, burning, itching and irritation.

DOSAGE AND ADMINISTRATION: Apply Vanamide to affected areas. Protect surrounding tissue. Smooth over affected tissue, nail or skin area(s) until cream is absorbed. If desired, cover with adhesive bandage or gauze, secured with adhesive tape. When applying to diseased or damaged nail surfaces, use an ample amount. Cover as above. An option is then to remove a "finger" from a plastic or vinyl glove and slip over the bandage-covered site. Secure glove finger with additional adhesive tape. Keep dry and occlusive for 3-7 days.

HOW SUPPLIED: Vanamide urea cream, 40% is supplied in: 85 gram tube, NDC 0066-0603-03 and 199 gram tube, NDC 0066-0603-07.

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

Protect from freezing.

Rx Only.

Prescribing Information as of September 2002.

**How to properly use
Vanamide™
urea cream, 40%**

Potent tissue-softener for skin or nails. Easy steps to help thin and soften thick, severely rough or dry skin, calluses and nail tissue, including ingrown nails.

1. Apply Vanamide to affected areas. Protect surrounding skin.
2. Smooth over affected skin area(s) until cream is absorbed. If desired, cover with adhesive bandage or gauze, secured with adhesive tape. When applying to diseased or damaged nail surfaces, use an ample amount. Cover as above. It is then advisable to remove the "finger" from a plastic or vinyl glove and slip over the bandage covered site. Secure glove finger with additional adhesive tape. Keep dry and occlusive for 3-7 days.
3. Use soap and water to wash off any excess product on unaffected skin areas, including hands. Avoid contact with eyes.

Manufactured for:

Dermik Laboratories

A Division of Aventis Pharmaceuticals Inc.
Berwyn, PA 19312 USA

by:

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DERMIK®