

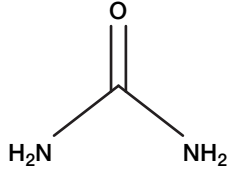
# ***U-Kera E™*** ***Urea Emollient Cream, 40%***

**Rx only**

**FOR TOPICAL USE ONLY.  
NOT FOR OPHTHALMIC USE.**

**DESCRIPTION:** *U-Kera E™* is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of *U-Kera E™* contains urea USP (40%), purified water USP, light mineral oil NF, white petrolatum USP, glycolic acid, propylene glycol USP, triolamine NF, glyceryl stearate SE, cetyl alcohol NF, L-arginine USP, and xanthan gum NF.

**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, 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 C. Animal reproduction studies have not been conducted with *U-Kera E™*. It also is not known whether *U-Kera E™* can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. *U-Kera E™* 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 *U-Kera E™* is administered to a nursing woman.

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

**ADVERSE REACTIONS:** Transient stinging, burning, itching and irritation may occur and normally disappear on discontinuing the medication.

**DOSAGE AND ADMINISTRATION:** Apply *U-Kera E™* 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:**

*U-Kera E™* Urea Cream, 40% is supplied in tubes containing 28.35 g (1 oz) NDC 51672-1329-2, 85.05 g (3 oz) NDC 51672-1329-8, and 198.45 g (7 oz) NDC 51672-1329-7.

**Store at 20°-25°C (68°-77°F)** [see USP Controlled Room Temperature]. Protect from freezing.

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