



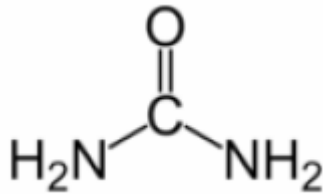
**FOR EXTERNAL USE ONLY.**

**Rx Only**

### **DESCRIPTION**

KERAFOAM<sup>®</sup> Emollient Foam is a keratolytic emollient foam which is a tissue softener for skin and/or nails. KERAFOAM Emollient Foam contains 30% urea USP in an aqueous based emollient foam vehicle. Each gram of KERAFOAM Emollient Foam contains 30% urea USP, ammonium lactate, cetyl alcohol NF, emulsifying wax NF, methylparaben NF, propylene glycol USP, propylparaben NF, purified water USP, steareth-10. Also contains: Propellant HFA-134a (1,1,1,2-tetrafluoroethane).

Urea USP is a diamide of carbonic acid with the following chemical structure:



### **CLINICAL PHARMACOLOGY**

Urea gently lyses/dissolves the intercellular matrix of surface skin cells loosening and allowing a shedding of rough, thickened and scaly hyperkeratotic skin. Urea also moisturizes and softens skin.

### **INDICATIONS**

For softening, smoothing and removing rough scaling hyperkeratotic skin in conditions such as xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

### **CONTRAINDICATIONS**

Known hypersensitivity to any of the listed ingredients. Discontinue use if hypersensitivity is observed.

### **WARNINGS**

**FOR EXTERNAL USE ONLY.** Avoid contact with eyes, lips or mucous membranes. **Keep out of the reach of children.** Contents under pressure. Do not puncture or incinerate container. Do not expose to temperatures above 120°F (49°C).

## **PRECAUTIONS**

**Information for patients:** 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 KERAFOAM Emollient Foam. It is not known whether KERAFOAM Emollient Foam can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. KERAFOAM Emollient Foam 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 KERAFOAM Emollient Foam is administered to a nursing woman.

## **ADVERSE REACTIONS**

Transient stinging, burning, itching or irritation may occur and normally disappear on discontinuing the medication.

## **DOSAGE AND ADMINISTRATION**

**Shake Vigorously, Tap Bottom of Can, and Prime Before Initial Use. Shake Vigorously and Tap Before Each Use.**

**To Prime:** After shaking, gently tap bottom of can onto palm of other hand or a solid surface at least 3 times. Hold the can upright, direct away from patient, and firmly depress the actuator for 1 to 3 seconds or until foam begins to dispense. (If foam does not dispense within 3 seconds: re-shake can, gently tap bottom of can onto a solid surface at least 3 times, and depress the actuator again until foam begins to dispense.)

**Before Each Use:** Shake vigorously and gently tap bottom of can onto palm of other hand or a solid surface at least 3 times.

**During Use:** Holding can upright, dispense KERAFOAM into palm of hand and apply to affected area twice per day, or as directed by a physician. Rub in until completely absorbed. Wipe off any excess foam from actuator after use.

## **HOW SUPPLIED:**

KERAFOAM Emollient Foam is supplied in a 60g (NDC# 16781-157-60) aluminum can.

Store at room temperature: 59° - 77°F (15° - 25°C).

Protect from freezing.

Store upright.

Manufactured For:



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**Patent Pending**

P/N: 2604-pf Rev. 3