

**INDICATIONS:** Keralac® Cream (urea 47%) is a prescription medicine that is applied to the skin to treat certain skin conditions, including dry, rough skin, xerosis (abnormal dryness of the skin), ichthyosis (dry, thickened, scaly or flaky skin), cracks or crevices in the skin, dermatitis (inflammation of the skin), eczema, psoriasis, keratoses (certain growths or thickening of the outer layer of skin), and calluses.

## Important Safety Information

Keralac Cream is not for everyone. You should not use Keralac Cream if you are allergic or are suspected to be allergic to urea or to any of the other ingredients.

### **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.**

Keralac Cream should be used as directed by your physician. It should not be used to treat any condition other than that for which it was prescribed. Keralac Cream is to be used only by the person for which it was prescribed. Do not share it with others.

If redness or swelling or rash develop in the area being treated or elsewhere, discontinue use and contact a physician. If your condition does not improve or becomes worse, check with your doctor.

**KERALAC CREAM IS FOR EXTERNAL USE ONLY AND IS NOT FOR USE IN THE EYES.** Avoid contact with the eyes, nose, mouth, genital area, and anus. If you get Keralac Cream in the eyes, rinse them immediately with a generous amount of cool water.

Before starting treatment with Keralac Cream, tell your doctor if you have any medical conditions, especially if any of the following apply to you: if you have allergies to medicines, foods or other substances, if you are pregnant, planning to become pregnant, or if you are breastfeeding. It is not known if Keralac cream will harm your unborn baby or if it passes into your breast milk.

The most common side effects of Keralac cream are temporary stinging, burning, itching, and irritation which normally disappear when this product is discontinued. Seek medical attention right away if any of these severe side effects occur: severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); redness; severe or persistent irritation.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider.

To report negative side effects, contact Mission Pharmacal Company at 1-800-298-1087 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see **XXXXXX** for full Prescribing Information.