

4" x 5.5"

Urea Cream 39%

Rx Only

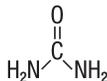
**FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.**

DESCRIPTION:

Urea Cream 39% is a keratolytic, emollient which is a gentle, yet potent, tissue softener for skin.

Each gram of Urea Cream 39% contains 39% urea as the active ingredient, as well as the following inactive ingredients: carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, sodium hydroxide, water, and xanthan gum.

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



INDICATIONS:

Urea Cream 39% is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

CONTRAINDICATIONS:

Urea Cream 39% is contraindicated for use by patients having known hypersensitivity to any component of this preparation.

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 of the skin.

PHARMACOKINETICS:

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

WARNINGS AND PRECAUTIONS:

FOR EXTERNAL USE ONLY.

Avoid contact with eyes, lips, and mucous membranes.

General: This product 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 and consult a physician.

Pregnancy: *Pregnancy Category C.*

Animal reproduction studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether or not this drug is excreted in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

ADVERSE REACTIONS:

Transient stinging, burning, itching or irritation may occur and normally disappear upon discontinuing the medication. **You should call your doctor for medical advice about side effects. To report a serious adverse event, call 1-855-899-4237.**

DOSAGE AND ADMINISTRATION:

Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed.

HOW SUPPLIED:

Urea Cream 39% is supplied in an 8 oz (227 g) bottle, NDC 42792-101-08.

Store between 15°C and 30°C (between 59°F and 86°F). Protect from freezing. Keep bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN.

Manufactured for:
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