

## How to properly use

R<sub>x</sub> Only

**CARMOL<sup>®</sup>4 O**  
(40% Urea)

Easy steps to gently thin and soften thick, rough or dry skin seen, to various degrees, in psoriasis, xerosis, ichthyosis, keratosis pilaris, keratosis palmaris, keratoderma, dermatitis, pruritus, eczema and calluses, as well as damaged, diseased or devitalized and ingrown nails.

### For skin:

1. Apply CARMOL<sup>®</sup>4 O to affected skin twice per day, or as directed by a physician.
2. Rub in until completely absorbed.

### For nail(s):

1. Apply CARMOL<sup>®</sup>4 O to affected nail(s) twice per day, or as directed by a physician.
2. Let dry uncovered or apply and cover with adhesive bandage or gauze secured with adhesive tape.

Rx Only

**CARMO<sup>4</sup>O**

(40% Urea) Lotion

Rx Only

**CARMO<sup>4</sup>O**

(40% Urea) Cream

Rx Only

**CARMO<sup>4</sup>O**

(40% Urea) GEL

**For external use only. Not for ophthalmic use.**

**DESCRIPTION:** CARMO<sup>4</sup>O is a keratolytic emollient which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of CARMO<sup>4</sup>O (40% Urea) Cream and CARMO<sup>4</sup>O (40% Urea) Lotion consists of 40% urea in a vehicle containing carbomer, cetyl alcohol, glyceryl stearate, mineral oil, petrolatum, propylene glycol, purified water, triethanolamine and xanthan gum. Each gram of CARMO<sup>4</sup>O (40% Urea) GEL consists of 40% urea in a vehicle containing disodium EDTA, glycerin, hydroxyethylcellulose, PEG-6 caprylic/capric glycerides, purified water, and xanthan gum.

Urea is a diamide of carbonic acid with the following 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 pilaris, keratosis palmaris, 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 B. Animal reproduction studies have revealed no evidence of harm to the fetus, however, there are no adequate and well-controlled studies in pregnant women. Because

animal reproduction studies are not always predictive of human response, CARMO<sup>4</sup>O 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. Because many drugs are excreted in human milk, caution should be exercised when CARMO<sup>4</sup>O is administered to a nursing woman.

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

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

**DOSAGE AND ADMINISTRATION:** Apply CARMO<sup>4</sup>O to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail(s) twice per day, or as directed by a physician. Let dry uncovered or apply and cover with adhesive bandage or gauze secured with adhesive tape.

**HOW SUPPLIED:** CARMO<sup>4</sup>O (40% Urea) is supplied as:

**CARMO<sup>4</sup>O Lotion:**  
236.6 mL (8 fl oz) bottle, NDC 10337-656-51

**CARMO<sup>4</sup>O Cream:**  
28.35 g (1 oz) tube, NDC 10337-652-52  
85 g (3 oz) tube, NDC 10337-652-19  
198.6 g (7 oz) tube, NDC 10337-652-49

**CARMO<sup>4</sup>O Gel:**  
15 mL (1/2 oz) bottle, NDC 10337-657-15

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

Protect from freezing.

Manufactured by **DERMarts** DIVISION



**DOAK DERMATOLOGICS**

A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

383 Route 46 West • Fairfield, NJ 07004-2402 USA  
1-800-405-DOAK • www.doakderm.com

Manufactured by:  
Groupe PARIMA, Inc.  
Montreal, QC H4S 1X6  
CANADA

Reg. U.S. Patent Nos.  
5,919,470  
6,380,236

IL129-R9  
Rev 09/06