



Lactic Acid 10% Lotion

For dry, itchy skin & minor
skin irritation

FOR EXTERNAL USE ONLY.

NOT FOR OPHTHALMIC USE.

Rx only

DESCRIPTION:

Lactic acid, an alpha-hydroxy acid, is a natural skin-moisturizing agent. It has beneficial effects on dry skin (xerosis) and in severe discomfort of hyperkeratotic conditions.

INGREDIENTS:

Active Ingredient:

Lactic Acid 10%.

Inactive Ingredients:

Purified Water, Isopropyl Palmitate, Cetyl Alcohol, Glyceryl Stearate / PEG-100 Stearate, Glycerin, PEG-40 Stearate, Caprylic / Capric Triglyceride, Lecithin, Dimethicone, Methylparaben, Edetate Disodium, Imudurea, Sodium Benzoate, Propylparaben.

INDICATIONS AND USAGE:

Lactic Acid 10% Lotion is a white rich moisturizer for dry skin (xerosis) and is indicated to moisturize and soften dry, itchy skin and minor skin irritation.

CONTRAINDICATION:

Not for use in patients known to be sensitive to the active or inactive ingredients in Lactic Acid 10% Lotion.

WARNINGS:

Minimize or avoid sun exposure to areas of the skin treated with Lactic Acid 10% Lotion.

PRECAUTIONS:

FOR EXTERNAL USE ONLY. KEEP OUT OF THE REACH OF CHILDREN. Do not use in or near eyes, lips or mucous membranes. Patient may experience mild, stinging or burning and peeling may occur on sensitive or irritated skin areas. If sensitivity or irritation occurs, immediately discontinue use and consult a medical professional. Due to potential irritation, do not use on the face. The potential for post-inflammatory hypo- or hyperpigmentation has not been studied.

Avoid administering Lactic Acid 10% Lotion to pregnant women unless clearly required and use caution in its use for nursing mothers. Safety and effectiveness in pediatric patients have not been established.

DOSAGE AND ADMINISTRATION:

Apply thoroughly twice daily on affected areas or as prescribed by a Physician.

Dispense in accordance with applicable state law. This product has not been approved by the FDA, is not listed in the Orange Book, and has not been approved or rated for therapeutic equivalence with any other product.

HOW SUPPLIED:

12 oz. (354.84mL) net wt. high density polyethylene bottle NDC 64980-310-36

16 oz. (473.12mL) net wt. high density polyethylene bottle NDC 64980-310-48

STORAGE:

Store at controlled room temperature 15°-30°C (59°-86°F). See bottle for lot number and expiration date.

Rx only

Manufactured by:

Groupe Parima, Inc.,

Montreal, QC H4S 1X6

Canada

Manufactured for:

Rising Pharmaceuticals, Inc.

Allendale, NJ 07401

IN-31036

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