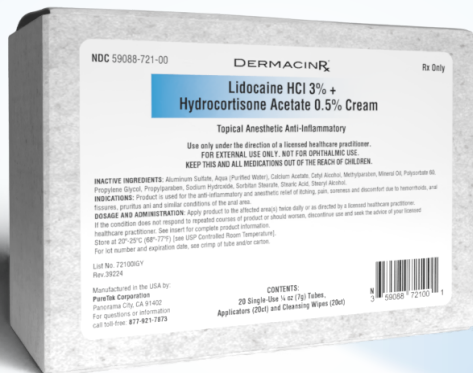


Lidocaine HCl 3% + Hydrocortisone Acetate 0.5% Cream

Topical Anesthetic Anti-Inflammatory

NDC: 59088-721-00



DERMACIN_{Rx}

Description:

Lidocaine HCl 3% + Hydrocortisone Acetate 0.5% Cream Kit is intended for the temporary relief of pain, itching, soreness, and discomfort associated with hemorrhoids, anal fissures, pruritus ani, and related conditions. It includes Lidocaine HCl 3% + Hydrocortisone Acetate 0.5% Cream (7g tubes), along with gentle cleansing wipes and easy-to-use applicators for clean, targeted application to the affected area.

Lidocaine HCl 3% + Hydrocortisone Acetate 0.5% Cream is formulated to ensure ease of use and hygiene, suitable for both at-home and on-the-go care.

Unit Detail:

20 Single-Use 1/4 oz (7 g) Tubes, Applicators and Cleansing Wipes

Dosage:

Apply to the affected area(s) twice daily or as directed by a licensed healthcare practitioner.

See reverse for complete prescribing information

Lidocaine HCl 3% + Hydrocortisone Acetate 0.5% Cream

ACTIVE INGREDIENTS: Lidocaine HCl 3%, Hydrocortisone Acetate 0.5%

INACTIVE INGREDIENTS: Aluminum Sulfate, Aqua (Purified Water), Calcium Acetate, Cetyl Alcohol, Methylparaben, Mineral Oil, Polysorbate 60, Propylene Glycol, Propylparaben, Sodium Hydroxide, Sorbitan Stearate, Stearic Acid, Stearyl Alcohol.

Indications and Usage: Indicated for the anti-inflammatory and anesthetic relief of itching, pain, soreness and discomfort due to hemorrhoids, anal fissures, pruritus ani and similar conditions of the anal area.

CONTRAINDICATIONS: Product should not be used in patients with a history of sensitivity to any of its ingredients or adverse reactions to lidocaine or amide anesthetics, which usually do not cross-react with “caine” ester type anesthetics. If excessive irritation and significant worsening occurs, discontinue use and seek the advice of your physician. Product and topical lidocaine should be used cautiously in those with impaired liver function, as well as the very ill or very elderly and those with significant liver disease. Product should be used with caution in patients receiving antiarrhythmic drugs of Class I since the adverse effects are additive and generally synergistic. Product is contraindicated for tuberculous or fungal lesions or skin vaccinia, varicella and acute herpes simplex. Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS: For external use only; not for ophthalmic use. Product and used applicators could harm small children if chewed or swallowed.

ADVERSE REACTIONS: During or immediately following application of product, there may be transient stinging or burning from open areas of skin, or transient blanching (lightening), or erythema (redness) of the skin.

Use under the direction of a licensed healthcare practitioner.

Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873**

HOW SUPPLIED:

Lidocaine HCl 3% + Hydrocortisone Acetate 0.5% Cream

Kit contains 20 Single-Use 1/4 oz (7 g) Tubes (NDC 59088-819-01), Applicators and Cleansing Wipes. NDC 59088-721-00

STORAGE:

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

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured by:

PureTek Corporation

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**