ADAPAL CREAM

(Adapalene)
TOPICAL RETINOID

DESCRIPTION

Adapal Cream contains adapalene, a retinoid-like compound for topical treatment of acne. Adapalene is a naphthoic acid derivative that modulates epidermal cell differentiation, keratinization and inflammatory processes associated with acne vulgaris.

COMPOSITION

Active ingredient: Adapalene. The concentration and excipient composition must correspond to the approved product formula and carton label. For external use only.

CLINICAL PHARMACOLOGY

Adapalene binds to selected nuclear retinoic acid receptors and helps normalize differentiation of follicular epithelial cells, reducing formation of microcomedones. It also has anti-inflammatory activity. Systemic absorption after topical application is low.

INDICATIONS

Adapal Cream is indicated for the topical treatment of acne vulgaris, including comedonal and inflammatory lesions, on areas such as the face, chest or back, as directed by a healthcare professional.

DOSAGE AND ADMINISTRATION

Apply a thin film to the acne-affected area once daily, preferably at bedtime, or as directed by the physician. Before application, gently cleanse the affected skin and allow it to dry. Apply sufficient cream to cover the entire affected area rather than individual spots. Wash hands after use.

Do not apply more frequently or in larger quantities than recommended: this will not speed improvement and may increase skin irritation. If a dose is missed, resume the regular schedule; do not double the quantity applied.

DURATION OF TREATMENT

Initial worsening of visible acne may occur during the first weeks. Improvement is gradual; consistent results may require 8-12 weeks. Reassess treatment after approximately three months or as advised by the physician.

CONTRAINDICATIONS

Hypersensitivity to adapalene or any component of the formulation. Do not use during pregnancy or when planning pregnancy.

WARNINGS AND PRECAUTIONS

General: For external use only. Not for use in the eyes, mouth or vagina. Avoid contact with eyelids, lips, corners of the nose and other mucous membranes. If accidental contact occurs, rinse thoroughly with lukewarm water.

Do not apply to cuts, abrasions, eczematous, broken or sunburned skin. Avoid waxing on treated areas because skin injury may occur. Use mild cleansers and non-comedogenic moisturizers if needed.

Skin dryness, redness, scaling, stinging, itching or burning may occur, especially during the first 2-4 weeks. If significant irritation develops, reduce the frequency or temporarily stop application and seek medical advice. Discontinue use and obtain prompt care if a severe allergic reaction occurs.

SUN EXPOSURE

Minimize exposure to strong sunlight and artificial UV light. Use suitable sunscreen and protective clothing when outdoors. Cold or windy weather may increase skin irritation.

DRUG INTERACTIONS

Concurrent use of abrasive cleansers, astringents, peeling agents, alcohol-containing preparations or products with alpha-hydroxy/glycolic acids may increase irritation. Other acne treatments, including benzoyl peroxide or topical antibiotics, should be combined only on professional advice; if prescribed together, different application times may be recommended.

PREGNANCY

Topical adapalene should not be used during pregnancy or while planning pregnancy. If pregnancy occurs during treatment, discontinue the cream and consult the physician.

LACTATION

Breastfeeding patients should consult their physician before use. Avoid applying to the breast or chest where an infant could have direct skin contact; prevent the infant from contacting treated areas.

PEDIATRIC USE

Use in children younger than 12 years has not been established for commonly referenced adapalene cream formulations. Use in adolescents should follow the approved local label and prescriber directions.

GERIATRIC USE

Clinical experience in older patients is limited. Use according to the physician's assessment.

ADVERSE REACTIONS

Common local reactions: Dryness, erythema (redness), skin irritation, burning or stinging. These are generally most noticeable early in treatment and may decrease with continued appropriate use.

Other reported reactions: Peeling, pruritus, skin discomfort, contact dermatitis, acne flare, sunburn, application-site pain or swelling, eyelid irritation, skin discoloration and application-site burns. Rare serious hypersensitivity may cause facial or throat swelling, rash, hives or breathing difficulty. Seek urgent medical attention in these circumstances.

OVERDOSAGE

Excessive topical use can cause marked redness, peeling and irritation without added benefit. Stop or reduce use and obtain medical advice if severe symptoms develop. In case of accidental ingestion, seek immediate medical advice; treatment is supportive.

EFFECTS ON DRIVING AND MACHINERY

No clinically important effects are expected from normal topical use.

STORAGE CONDITIONS

Store below 25°C unless otherwise stated in the approved product specification. Protect from freezing and excessive heat. Keep the tube tightly closed. Keep all medicines out of the reach of children.

PRESENTATION

Adapal Cream: 15 g tube.

IMPORTANT

Use only as directed by a registered medical practitioner. Refer to the approved carton for strength, batch number, manufacturing date and expiry date.

Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore - Pakistan.