VEGATREX GEL

(Isotretinoin + Erythromycin)

COMPOSITION

Each 1 g of gel contains Isotretinoin 0.5 mg (0.05% w/w) and Erythromycin 20 mg (2% w/w). Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Isotretinoin is a topical retinoid that normalises follicular epithelial differentiation, reduces comedone formation and helps prevent blocked pores. Erythromycin is a macrolide antibiotic that inhibits bacterial protein synthesis and reduces susceptible acne-associated bacteria. The combination acts on inflammatory and non-inflammatory acne lesions.

INDICATIONS

Topical treatment of mild to moderate acne vulgaris in adults and adolescents aged 12 years and older, subject to locally approved indications and antimicrobial prescribing guidance.

DOSAGE & ADMINISTRATION

For external use only. Gently cleanse the affected skin with a mild cleanser and allow it to dry. Apply a thin film to the affected area once or twice daily, as prescribed. Wash hands after application. Avoid eyes, lips, nostrils and other mucous membranes.

Treatment response may take 6-8 weeks. The prescriber should reassess continued antibiotic use, especially beyond 12 weeks.

APPLICATION GUIDANCE

Apply only a thin layer. Excess application does not improve results and may increase irritation. If dryness or irritation occurs, a non-comedogenic moisturiser may help; consult the prescriber about reducing frequency or temporarily withholding treatment.

Do not apply to cuts, eczema, sunburn or broken or irritated skin. If accidental contact with the eyes or mucous membranes occurs, rinse thoroughly with water.

PAEDIATRIC USE

Safety and effectiveness have not been established in children younger than 12 years.

CONTRAINDICATIONS

Hypersensitivity to isotretinoin, erythromycin or any component of the formulation. Contraindicated during pregnancy and in women planning pregnancy.

PREGNANCY & LACTATION

Do not use during pregnancy or while planning pregnancy. Stop treatment and seek medical advice if pregnancy occurs. Safety during breastfeeding is not established; the clinician should decide whether to discontinue breastfeeding or treatment. Avoid application to the breast and areas that could contact the infant.

THERAPEUTIC CLASS

Topical retinoid + macrolide antibiotic. Primary medical segment: Dermatology (acne management).

WARNINGS & PRECAUTIONS

Topical isotretinoin may increase sensitivity to sunlight. Minimise sun exposure, avoid sunlamps and use broad-spectrum sunscreen and protective clothing. Wind, cold weather and irritating cosmetics may worsen dryness or redness.

Avoid simultaneous use of abrasive cleansers, strong astringents, alcohol-based products, peeling agents and other irritating topical acne treatments unless advised by a clinician.

Antibiotic use may encourage resistant organisms. If superinfection occurs, stop treatment and seek medical advice. Severe or persistent diarrhoea or abdominal cramps during or after treatment require assessment for antibiotic-associated colitis, although this is uncommon with topical use.

DRUG INTERACTIONS

Avoid concurrent topical clindamycin because antagonism may occur. Benzoyl peroxide and other oxidising agents may reduce isotretinoin activity; if both are prescribed, apply at separate times. Other topical retinoids, keratolytics and exfoliants can increase irritation.

ADVERSE REACTIONS

Common reactions include dryness, redness, scaling, peeling, burning, stinging, itching, irritation and local discomfort. Less common reactions include photosensitivity, skin colour changes, contact dermatitis and allergic reactions. Stop and seek advice for severe irritation, swelling or rash.

OVERDOSAGE

Excessive topical use may cause marked redness, peeling and discomfort. Wash off excess gel and seek medical advice if symptoms persist. If accidentally swallowed, seek urgent medical assistance; gastrointestinal symptoms may occur.

STORAGE CONDITIONS

Store below 25 degrees C unless the approved product specifications state otherwise. Protect from heat and direct sunlight. Keep the tube tightly closed and out of reach of children. Do not use after the expiry date.

PRESENTATION

Vegatrex Gel: Isotretinoin 0.05% w/w + Erythromycin 2% w/w, 10 g tube.

PATIENT ADVICE

Use only as directed. Do not share this medicine. Improvement is gradual; continue only for the prescribed duration. Protect skin from sunlight and avoid irritating cosmetics. Inform your doctor if you become pregnant, experience severe irritation, or develop prolonged diarrhoea.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.