GEN-B CREAM

(Gentamicin 0.1% w/w + Betamethasone 0.1% w/w)

COMPOSITION

Each gram contains Gentamicin 1 mg (0.1% w/w) and Betamethasone 1 mg (0.1% w/w), in a suitable cream base. The exact salt/ester forms must conform to the approved product specifications.

DESCRIPTION

Gen-b Cream combines an aminoglycoside topical antibiotic with a corticosteroid for external application to the skin.

CLINICAL PHARMACOLOGY

Gentamicin exerts bactericidal activity through binding to the bacterial 30S ribosomal subunit and disruption of protein synthesis. It acts against susceptible aerobic bacteria, including some Staphylococcus and Gram-negative organisms. Betamethasone produces anti-inflammatory, antipruritic and vasoconstrictive effects. Corticosteroid absorption can increase when applied to damaged skin, large areas or under occlusive dressings.

INDICATIONS

For short-term management of corticosteroid-responsive inflammatory dermatoses complicated by, or at risk of, secondary infection due to gentamicin-susceptible bacteria, when both an antibiotic and a corticosteroid are clinically indicated. Examples may include infected eczema and dermatitis. Bacterial infection should be clinically assessed; not for routine treatment of simple acne or fungal/viral dermatoses.

DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area once or twice daily, or as directed by a physician. Gently rub in. Use the smallest effective quantity over the shortest appropriate course. Review treatment if symptoms worsen, spread or do not improve; prolonged or repeated courses should be avoided. The precise duration should follow the approved prescribing information.

DIRECTIONS FOR USE

Clean and dry the affected area before application. Wash hands after applying, unless the hands are the treatment site. For external use only. Avoid contact with the eyes, mouth and other mucous membranes. Do not cover with tight or occlusive dressings unless prescribed.

CONTRAINDICATIONS

Hypersensitivity to gentamicin, betamethasone, other aminoglycosides or formulation components. Untreated fungal or viral skin infections, including herpes simplex, varicella and vaccinia; cutaneous tuberculosis; rosacea and perioral dermatitis. Do not use for ocular treatment.

WARNINGS AND PRECAUTIONS

Avoid use on extensive skin areas, open wounds, ulcerated skin or burns unless specifically supervised. Local corticosteroids can mask signs of infection, delay healing or cause rebound symptoms. Excessive or prolonged use may lead to skin atrophy, stretch marks, telangiectasia, acneiform eruptions and systemic corticosteroid effects. Stop and reassess if irritation, sensitization or superinfection occurs.

ANTIBIOTIC PRECAUTIONS

Unnecessary or prolonged gentamicin exposure can encourage resistant organisms or fungal overgrowth. Bacteria not susceptible to gentamicin may not respond. Systemic absorption of aminoglycosides can occur on extensive damaged skin, particularly in patients with renal impairment, although this is uncommon with limited intact-skin use.

FACE, EYES AND SKIN FOLDS

Avoid prolonged use on the face, around the eyes, skin folds or genital area without explicit medical advice. Corticosteroids near the eyes may cause ocular complications such as increased intraocular pressure or cataract. Seek assessment for blurred vision or other visual disturbances.

PEDIATRIC USE

Children are more susceptible to systemic effects of topical corticosteroids because of a larger skin surface area relative to body weight. Avoid use under diapers or occlusive coverings. Use only under physician supervision and for the shortest appropriate period.

DRUG INTERACTIONS

Clinically important interactions are not expected with limited topical application, but concurrent irritating topical products may increase local reactions. Inform the prescriber of other creams, ointments or medicines applied to the same area.

PREGNANCY

Adequate controlled human studies of the combination are limited. Use only when expected benefit justifies potential risk and under medical advice. Avoid large areas, occlusion and prolonged courses, particularly during pregnancy.

LACTATION

Use cautiously on limited areas where clinically necessary. Do not apply to the breast or areas likely to contact the infant. Avoid exposing the infant to treated skin.

ADVERSE REACTIONS

Application-site burning, itching, redness, dryness, irritation or allergic contact dermatitis may occur. Prolonged corticosteroid use may cause skin thinning, striae, discoloration, telangiectasia, steroid acne, perioral dermatitis and secondary infection. Rarely, with extensive use or occlusion, hypothalamic -pituitary-adrenal suppression, hyperglycemia or other systemic steroid effects may occur. Stop use and seek advice for marked rash, swelling or worsening infection.

OVERDOSAGE

Excessive or prolonged application may result in systemic corticosteroid effects or overgrowth of nonsusceptible organisms. Discontinue or reduce exposure under medical supervision and treat symptomatically. In case of accidental ingestion, seek medical advice.

EFFECT ON DRIVING AND MACHINERY

No significant effect on driving or operating machinery is expected from appropriate topical use.

STORAGE CONDITIONS

Keep tube tightly closed. Protect from excessive heat and light. Store according to the temperature specified on the approved pack. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Gen-b Cream, 15 g tube.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.