FUSIBACT CREAM

(Fusidic Acid 20 mg/g - 2% w/w)

COMPOSITION

Each 1 g cream contains Fusidic Acid 20 mg (2% w/w). Each 15 g tube contains 300 mg fusidic acid in total. Other ingredients: according to the approved product formulation.

DESCRIPTION

Fusibact Cream is a topical antibacterial preparation containing fusidic acid, a steroidal-structure antibiotic of the fusidane group. Intended for cutaneous use only.

PHARMACOLOGY

Fusidic acid inhibits bacterial protein synthesis through interference with elongation factor G (EF-G), thereby preventing bacterial growth. It is active against susceptible organisms, particularly Staphylococcus aureus. In-vitro studies show penetration through intact skin; systemic exposure after normal topical application is low.

INDICATIONS

Treatment of localized, superficial bacterial skin infections caused by susceptible organisms. Examples include impetigo, superficial folliculitis, sycosis barbae, paronychia and erythrasma. Some reference formulations also treat secondary infection of eczema, dermatitis, and minor cuts or abrasions. Treatment selection should follow local antimicrobial guidance.

DOSAGE AND ADMINISTRATION

Adults and children: Gently apply a thin layer to the affected skin three or four times daily when lesions are left uncovered. Less frequent application may be sufficient under a covering, as directed by a clinician. Duration depends on infection and clinical response; avoid unnecessary extended or repeated courses.

METHOD OF APPLICATION

Clean and dry the affected area as appropriate. Apply gently using clean hands. Wash hands afterwards unless treating the hands. Avoid contact with eyes, mouth and other mucous membranes. For external use only.

CONTRAINDICATIONS

Known hypersensitivity to fusidic acid or any component of the formulation.

WARNINGS AND PRECAUTIONS

Prolonged or repeated treatment may promote bacterial resistance and contact sensitization. Do not use for infections caused by nonsusceptible organisms, notably Pseudomonas aeruginosa. Avoid the eyes, as conjunctival irritation can occur. Stop use and seek medical advice if allergy develops or infection worsens. Do not share the medicine.

EXCIPIENT PRECAUTIONS

Certain reference formulations contain cetyl alcohol, butylhydroxyanisole, potassium sorbate or polysorbate 60, which can cause local irritation or allergic reactions. Applicable warnings depend on the actual Fusibact formulation and its excipients.

DRUG INTERACTIONS

No formal interaction studies have been performed for the topical preparation. Clinically important interactions with systemic medicines are unlikely during normal use because systemic absorption is minimal. Inform the prescriber about other products being used on the same area.

PREGNANCY

Reference product information indicates no anticipated fetal effects from topical fusidic acid because systemic exposure is negligible. Use during pregnancy under medical advice and only as clinically appropriate.

LACTATION

Topical fusidic acid may be used during breastfeeding when appropriate; avoid application to the breasts or any area that may contact the infant directly. Seek advice if treatment of a large area is needed.

PEDIATRIC USE

Reference labeling permits use in children, using the same topical application principles as adults. Infants and young children should be treated under medical supervision.

ADVERSE REACTIONS

Uncommon reactions: itching, redness, rash, eczema/contact dermatitis, application-site burning, pain or irritation. Rare reactions: hypersensitivity, urticaria, blisters, angioedema or conjunctivitis. Stop application and obtain medical help for severe allergic symptoms.

OVERDOSAGE

Overdose with topical use is unlikely. If excessive cream is applied, remove the excess. If accidentally swallowed, particularly by a child, contact a medical professional or poison information service for advice; management is symptomatic.

EFFECT ON DRIVING AND MACHINERY

Topical fusidic acid has no or negligible effect on ability to drive or operate machinery.

STORAGE CONDITIONS

Keep the tube tightly closed, protected from excessive heat, and out of the reach of children. Follow the storage temperature and in-use period specified on the approved pack. Do not use after the expiry date.

PRESENTATION

Fusibact Cream, 2% w/w, in a 15 g tube.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.