

BACTIREST CREAM PRESCRIBING INFORMATION

Fusidic Acid 2% Cream

COMPOSITION

Bactirest Cream

Each g contains:	
Fusidic Acid I.P.	20 mg
Potassium Sorbate B.P. [as preservative]	2.7 mg
In a Translipid cream base	

DESCRIPTION

Fusidic acid is an antibiotic derived from *Fusidium coccineum*. It exerts powerful antibacterial activity against a number of Gram-positive organisms. Staphylococci, including the strains resistant to penicillin or other antibiotics, are particularly susceptible to Fusidic acid.

Translipid cream base is a unique combination of 70% lipids dispersed in 30% water. It spreads better, helps the active ingredient to stay longer and penetrate faster, giving the power of an ointment with the comfort of a cream.

CLINICAL PHARMACOLOGY

The therapeutic efficacy of topically applied Fusidic acid is due partly to the pronounced antibacterial activity against organisms responsible for skin infections and partly to the unique ability of this antibiotic to penetrate intact skin.

Fusidic acid inhibits bacterial protein synthesis by interfering with amino acid transfer from aminoacyl-sRNA to protein on the ribosomes. Fusidic acid may be bacteriostatic or bactericidal depending on inoculum size. Although bacterial cells stop dividing almost within 2 minutes after contact with the antibiotic *in vitro*, DNA and RNA synthesis continue for 45 minutes and 1 to 2 hours, respectively.

Fusidic acid is virtually inactive against gram-negative bacteria. The differences in activity against gram-negative and gram-positive organisms are believed to be due to a difference in cell wall permeability.

Mammalian cells are much less susceptible to inhibition of protein synthesis by fusidic acid than sensitive bacterial cells. These differences are believed to be due primarily to a difference in cell wall permeability.

INDICATIONS

The treatment of primary and secondary skin infections caused by *Staphylococcus aureus*, *Streptococcus species*, *C. minutissimum*, *Propionibacterium acnes* and other organisms sensitive to Fusidic acid.

Primary skin infections that may be expected to respond to treatment with **Bactirest Cream** include: impetigo contagiosa, boils, carbuncles, folliculitis, sycosis barbae, hidradenitis, acne, erythrasma, paronychia and secondary skin infections such as infected wounds and infected burns.

Appropriate culture and susceptibility studies should be performed. However, while waiting results of these studies and, if antibiotic therapy is considered to be necessary, **Bactirest Cream** may be administered to those patients in whom an infection caused by susceptible bacteria is suspected. This antibiotic treatment may subsequently require modification once these results become available.

In addition, local concentrations of topical fusidic acid are active against other *Corynebacteria*, *Neisseria*, *Clostridia* and *Bacteroides* species. No cross-resistance has been observed to date between fusidic acid and other antibiotics presently in clinical use.

CONTRA-INDICATIONS

Sensitivity to fusidic acid and its salts, or any ingredient in the formulation. Infection caused by non-susceptible organisms, in particular, *Pseudomonas aeruginosa*.

PRECAUTIONS

- ✓ Treatment of severe or refractory skin lesions should be supplemented with the administration of a systemic antibacterial agent.
- ✓ Use of topical antibiotics occasionally allows overgrowth of non-susceptible organisms. If this occurs, or irritation or sensitization develops, treatment should be discontinued and appropriate therapy instituted.
- ✓ Fusidic acid topical preparations should not be used in or near the eye because of the possibility of conjunctival irritation.

Pregnancy: Safety in the treatment of infections during pregnancy has not been established. Animal studies and many years of clinical experience have suggested that fusidic acid is devoid of teratogenic effect. There is evidence to suggest that when given systemically, fusidic acid can penetrate the placental barrier. If administration to pregnant patients is considered necessary, its potential benefits should be weighed against the possible hazards to the fetus.

Lactation: Safety in nursing mothers has not been established. When fusidic acid (as the sodium salt) has been given systemically, levels have been detected in breast milk, but with topical use the possible amount of drug present is unlikely to affect the infant. **Bactirest Cream** can be used during breast feeding.

SIDE EFFECTS

Mild irritation has occasionally been reported in patients with dermatoses treated with fusidic acid. It was not usually necessary to discontinue therapy. The application of fusidic acid to deep leg ulcers has been associated with pain. Reports of hypersensitivity reactions have been rare.

DOSAGE & ADMINISTRATION

Apply a small amount of **Bactirest Cream** to the lesion 3 or 4 times daily until favorable results are achieved. Whenever the lesion is to be covered with a gauze dressing, less frequent applications (1 or 2 daily) may be used.

In impetigo contagiosa, it has not been shown necessary to remove the crusts before application.

When required, incision and drainage of infected skin lesions should be carried out before treatment with fusidic acid.

PRESENTATION

Bactirest Cream is available in tubes of 5g and 10g.

STORAGE

Store at a temperature not exceeding 25°C.