



Presentation

Fucimax [™]Tablet: Each tablet contains Sodium Fusidate BP 250 mg.

Sodium Fusidate is a potent anti-staphylococcal agent with unusual ability to penetrate tissue. Bactericidal levels have been assayed in bone and necrotic tissue. Concentrations of 0.03 - 0.12 micrograms/ml inhibit nearly all strains of Staphylococcus aureus. Fusidic acid is active against Staphylococcus epidermidis and methicillin-resistant staphylococci.

Indications and Uses

Sodium Fusidate is indicated in the treatment of all staphylococcal infections due to susceptible organisms such as:

- · cutaneous infections
- · osteomyelitis
- · pneumonia
- · septicaemia
- · wound infections
- · endocarditis
- superinfected cystic fibrosis

Dosage and administration

For staphylococcal skin infections:

Tablet

Adults and children from 12 years: 250 mg 2 times a day for 5-10 days.

For penicillin-resistant staphylococcal infections such as osteomyelitis, pneumonia, septicemia, wound infections, endocarditis, superinfected cystic fibrosis: Tablet

Adults and children from 12 years: 500 mg 3 times a day. Dose can be increased to 1 gram 3 times a day for severe infections.

Oral suspension³

Children 1-11 months: 15 mg/kg 3 times a day

Children 1-4 years: 250 mg 3 times a day Children 5-11 years: 500 mg 3 times a day

Children 12-17 years: 750 mg 3 times a day

Adults: 750 mg 3 times a day

*Oral suspension is not available for Fucimax.

Elderly:

No dosage adjustment is necessary in the elderly.

Since Sodium Fusidate is excreted in the bile, no dosage modifications are needed in renal impairment.

No dosage adjustment is required in patients undergoing haemodialysis as it is not significantly dialysed.

Side-effects

The most frequently reported undesirable effects to Sodium Fusidate are dose dependent gastrointestinal disorders like diarrhoea, vomiting, abdominal pain, dyspepsia, nausea. Various skin reactions, reversible jaundice, haematological disorders and generalised hypersensitivity reactions have been reported. Leukopenia, thrombocytopenia, anemia, anorexia, drowsiness, dizziness, headache, cholestasis, urticaria, pruritus, rash, rhabdomyolysis may rarely occur.

Precautions

Periodic liver function tests should be carried out when the product is given for prolonged periods and to patients with liver dysfunction.

Use in pregnancy & lactation

Pregnancy: Based on animal data does not cause fetal harm. Do not use unless the potential benefit justifies the potential risk.

Lactation: Caution should be exercised when administered to a nursing woman.

Hypersensitivity to any of the ingredients of this formulation. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Drug interactions

Statin treatment should be discontinued throughout the duration of the Sodium Fusidate treatment. Co-administration of Sodium Fusidate systemically and Ciclosporin has been reported to cause increased plasma concentration of Ciclosporin.

Acute symptoms of overdose include gastrointestinal disturbances and possible effects on liver function. Treatment should be restricted to symptomatic and supportive measures.

Do not store above 30° C. Keep out of the reach of children.

Commercial Pack

Fucimax™ Tablet: Each box contains 1 blister strip of 10 tablets.

