

FACID[®]

Sodium Fusidate BP Film Coated Tablet

DESCRIPTION

Facid[®] is a preparation of Sodium Fusidate. Sodium Fusidate is a Sodium salt form of Fusidic Acid. Fusidic acid is an antibiotic derived from the fungus *Fusidium coccineum*. The mode of action is by inhibition of protein synthesis by the prevention of translocation on the ribosome. Concentrations adequate for bactericidal activity against Staphylococci after oral or parenteral administration have been demonstrated in the following: pus, exudate, soft tissue, bone tissue, synovial fluid, aqueous humour, vitreous body, burn crusts, intracranial abscess, sputum and serum.

INDICATIONS

Treatment of localized, as well as generalized staphylococcal infections (e.g. abscesses, furunculosis, wound infections, pneumonia, peritonitis, osteomyelitis, septicaemia, enteritis and otorhinolaryngeal infections).

In severe infections, deep-seated infections, infections due to methicillin-resistant Staphylococci or when prolonged therapy may be required, Sodium Fusidate must be given concurrently with other anti-staphylococcal antibiotic therapy.

DOSAGE AND ADMINISTRATION

Facid[®] tablet should be taken without a meal to avoid a reduction in the extent and rate of absorption of **Facid[®]** by a concomitant meal.

- **For community-acquired mild to moderate acute skin and skin-structure infections:** For adults 250 mg twice daily.
- **For all other infections caused by *Staphylococcus aureus*,**
 - Adults: 2x250 mg (2 tablets) three times daily.
 - Children 5 to 12 years: 250 mg three times daily

CONTRAINDICATIONS

- Concomitant treatment with statins
- Hypersensitivity to Fusidic Acid or its salts.

WARNINGS & PRECAUTIONS

Sodium Fusidate must not be co-administered with statins. There have been reports of rhabdomyolysis (including some fatalities) in patients receiving this

combination. In patients where the use of systemic Sodium Fusidate is considered essential, statin treatment should be discontinued throughout the duration of treatment. The patient should be advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain or tenderness. Statin therapy may be re-introduced seven days after the last dose of Sodium Fusidate.

PREGNANCY AND LACTATION

Pregnancy

Pregnancy Category C. In reproduction studies, mating frequency and fertility were normal and the offspring showed no morbid changes. As a precautionary measure, it is preferable to avoid the use of systemic Sodium Fusidate during pregnancy.

Lactation

Safety in lactation has not been established. There is evidence that the drug can penetrate the placental barrier and is detectable in human milk. Caution is therefore required when it is used in mothers who wish to breast feed.

SIDE EFFECTS

- Nausea & Vomiting
- Diarrhoea
- Dyspepsia
- Abdominal discomfort and pain
- Anaphylactic shock

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Facid[®] tablet: Box containing 1 strip of 10 tablets. Each film coated tablet contains Sodium Fusidate BP 250 mg.

SK+F

Manufactured by
ESKAYEF BANGLADESH LIMITED
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