



## FOBAN CREAM AND OINTMENT

### NAME AND STRENGTH OF ACTIVE SUBSTANCES :

**Cream:** Fusidic Acid 2% w/w.

**Ointment:** Sodium Fusidate 2% w/w.

### PRODUCT DESCRIPTION :

**Cream:** A white cream.

Other ingredients: Propyl Paraben, Methyl Paraben, White Soft Paraffin, Cetostearyl Alcohol, Cetomacrogol 1000 (Macrogol Cetostearyl Ether), Propylene Glycol, Liquid Paraffin and Purified Water.

**Ointment:** A colourless ointment.

Other ingredients: Liquid Paraffin and White Soft Paraffin.

**PHARMACODYNAMICS :** Fusidic acid and its salts exert antibacterial activity against most Gram positive organisms; in particular, they are effective against pathogenic Staphylococci, including the penicillinase-producing strains. They have slight or no activity against Gram negative organisms and fungi.

**PHARMACOKINETICS :** Fusidic acid and its salts are widely distributed into tissues and body fluids, including bone, pus, and synovial fluid; they penetrate cerebral abscesses but do not enter cerebrospinal fluid in appreciable amounts. They have been found in foetal circulation and in breast milk. About 95% or more of Fusidic acid or Sodium fusidate in the circulation is bound to plasma protein. Fusidic acid or Sodium fusidate is excreted in the bile, almost entirely as metabolites, some of which have weak antimicrobial activity. About 2% appears unchanged in the faeces. Little is excreted in the urine or removed by haemodialysis.

**INDICATIONS :** Skin lesions primarily or secondarily infected with *Staphylococcus* or *Streptococcus*.

**CONTRAINDICATIONS :** Known hypersensitivity to Fusidic acid, its salts and propylene glycol.

**DRUG INTERACTIONS :** No synergy has been demonstrated in vitro in most studies between Fusidic acid and rifampicin or vancomycin, and antagonism of the effects of ciprofloxacin has been reported. Interactions with the penicillins are complex, with either antagonism of the effect of one or both agents, or lack of any effect. However, the combination of an antistaphylococcal penicillin with Fusidic acid may prevent the emergence of Fusidic acid-resistant staphylococcal mutants, and such combinations may be clinically effective.

**ADVERSE EFFECTS :** Hypersensitivity reactions in the form of rashes and irritation may occur after the topical administration of Fusidates; rash is rare after systemic administration.

**WARNINGS AND PRECAUTIONS :** 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 eyes because of the possibility of conjunctival irritation.

**Pregnancy and Lactation :** Safety in the treatment of infections during pregnancy has not been established. If administration to pregnant patients is considered necessary, its potential benefits should be weighed against the possible hazards to the foetus. There is evidence to suggest that when given systemically, the drug can penetrate the placental barrier. The use of Foban in pregnancy requires that the potential benefits be weighed against the possible hazards to the foetus.

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.

**ROUTE OF ADMINISTRATION :** Topical.

**RECOMMENDED DOSAGE :** After washing, apply to the affected area twice daily as directed by your doctor or pharmacist.

### SYMPTOMS AND TREATMENT FOR OVERDOSE :

Overdosage has not been known to occur during topical therapy with Fusidic acid or its salts.

**PACKING :** 5g and 15g collapsible aluminium tubes.

**STORAGE :** Keep container well closed. Protect from light. Store below 30°C.

For external use only. Keep out of reach of children.

Recommended shelf-life: 3 years.

### MANUFACTURED BY :

HOE Pharmaceuticals Sdn. Bhd.

Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman,

42000 Port Klang, Selangor, MALAYSIA.

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