

## **Fucidin® I.V. INFUSION**

Physician's insert

**DRUGS-ABOUT.COM**

### **Presentation**

A pack of 2 vials

- one vial contains 500 mg Sodium Fusidate as a dry powder
- the second vial contains 10 ml sterile phosphate - citrate buffer solution (pH 7.4-7.6) with transfer needles.

### **Properties**

Fucidin is an antibiotic with a powerful antibacterial activity against a number of gram-positive microorganisms. Staphylococci, including the strains resistant to penicillin, methicillin or other antibiotics, are particularly susceptible to Fucidin. Fucidin shows no cross-resistance to any other antibiotic agent used in clinical practice.

Fucidin is widely distributed in the organism. It is of great clinical importance that Fucidin provides high concentration not only in areas well supplied with blood, but also in relatively avascular tissue. Concentrations exceeding the M.I.C. for Staphylococcus aureus (0.03-0.16 mcg/ml) have been found in pus, sputum, soft tissue, heart tissue, bone tissue, synovial fluid, sequestra, burn crusts, brain abscesses and intraocularly.

Fucidin is mainly excreted in the bile, little or none being excreted through the urine.

Fucidin can be used in cases where other antibiotics are contraindicated, e.g. in patients allergic to penicillin or other antibiotics and in patients with impaired renal function.

Fucidin shows no cross-hypersensitivity to other antibiotics in clinical use.

In severe or deep-seated infections and when prolonged therapy is required, systemic Fucidin should generally be given concurrently with other antistaphylococcal antibiotic therapy to minimize the risk of resistance development. Fucidin may be combined with penicillinase-stable penicillins, cephalosporins, erythromycin, rifampicin or lincomycin and thus an additive or synergistic effect is also obtained.

### **Indications**

Fucidin is indicated for the treatment of staphylococcal infections, e.g. osteomyelitis, septicaemia, endocarditis, cystic fibrosis, pneumonia, cellulitis, surgical and traumatic wound infections.

### **Dosage and Administration**

Fucidin may be given as intravenous infusion whenever oral therapy is inappropriate, including cases where absorption from the gastrointestinal tract is unpredictable.

- Adults: 500 mg (1 vial) 3 times daily
- Children and infants: 20 mg/kg/day divided into 3 equal doses.

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

The dosage in patients undergoing haemodialysis needs no adjustment as Fucidin is not significantly dialysed.

- Dosage in the elderly: No dosage alterations are necessary in the elderly.

If additional anti-bacterial therapy is to be employed, it is recommended that for parenteral administration separate infusion fluids be used.

Dissolve 1 vial of Sodium fusidate (500 mg) in the 10 ml of buffer solution provided. Dilute to 250-500 ml with Sodium chloride injection or 5% Dextrose injection BP.

Opalescence may be encountered with more acidic samples of dextrose and the solution should then be discarded. The diluted fluid should be infused via a central venous line over 2 hours. If the superficial vein is employed, a more prolonged period of at least 6 hours is advisable.

Fucidin infusion should be made into a wide-bore vein with good blood flow or through a central venous catheter to minimize the risk of venospasms and thrombophlebitis.

For adults a total daily dose of 2 g should not be exceeded.

The infusion solution should be used within 24 hours.

**Contra-indications, warnings, etc.**

Contra-indications: Contra-indicated in patients with known hypersensitivity to fusidic acid and its salts.

Intravenous Fucidin should not be infused with amino-acid solution or in whole blood.

Due to local tissue injury, Fucidin should not be administered intramuscularly or subcutaneously.

Incompatibilities: Infusion solutions containing Fucidin are incompatible with kanamycin, gentamicin, vancomycin, cephaloridine, carbenicillin, whole blood, amino-acid solutions and calcium-containing solutions.

Precipitation of fusidic acid may occur in infusion solutions with pH values below 7.5.

The solution of Fucidin in the buffer must never be injected undiluted.

**Precautions**

As Fucidin is metabolized in the liver and excreted mainly through the bile, periodic liver function tests should be carried out in patients with liver dysfunction, abnormalities in the biliary pathway or when Fucidin is given in high doses for prolonged periods, or when it is given in combination with other antibiotics which have similar excretion pathways e.g. lincomycin and rifampicin. Fucidin potentiates the anticoagulant efficacy of coumarin derivatives.

In vitro, Fucidin displaces bilirubin from its albumin binding site. The clinical significance of this finding is uncertain and kernicterus has not been observed in neonates receiving Fucidin. However, this observation should be borne in mind when the drug is given to preterm jaundiced, acidotic or seriously ill neonates.

**Pregnancy and Lactation**

Animal studies and many years of clinical experience suggest that Fucidin is devoid of teratogenic effects. Fucidin passes the placenta and should be avoided during third trimester due to the theoretical risk of kernicterus. Concentrations of Fucidin found in breast milk are negligible and its use is not contraindicated in nursing mothers.

**Side Effects**

Reversible jaundice has been reported in some patients, particularly in the young and elderly after administration of Fucidin, most frequently in patients receiving intravenous Fucidin in high dosage or when the drug has been infused too rapidly or at too high concentration in the infusion fluid. In some cases, instituting oral therapy may be beneficial. If the jaundice persists, Fucidin should be withdrawn, after which the serum bilirubin will return to normal. Allergic reactions are reported in very few cases.

**Overdosage**

Treatment should be restricted to symptomatic and supportive measures. Dialysis is of no benefit, since the drug is not significantly dialysed.

Manufacturer: Leo Pharmaceutical Products- Denmark.

Importer: Discotrade LTD, P.O.B 50 Hadera 38100.

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