Flucloxin®

Flucloxacillin capsule/powder for syrup

DESCRIPTION

Flucloxin® is a preparation of Flucloxacillin. It is active against Gram-positive organisms including penicillinase-producing strains. After an oral dose peak plasma concentrations are achieved in about one hour in fasting subjects. About 95% of Flucloxacillin in the circulation is bound to plasma proteins and its plasma half life is approximately one hour. Flucloxacillin is metabolised to a limited extent and the unchanged drug is excreted mainly in urine.

INDICATIONS

Flucloxacillin is indicated for the treatment of infections due to Gram-positive organisms, including infections caused by β-lactamase producing *staphylococci* including otitis externa, adjunct in pneumonia, impetigo, cellulitis, osteomyelitis and in staphylococcal endocarditis. Typical indications include:

Skin and soft tissue infections:

Boils, abscesses, carbuncles, infected skin conditions, e.g. ulcer, eczema and acne. Furunculosis, cellulitis, infected wounds, infected burns, protection for skin grafts, otitis media and externa, impetigo.

Respiratory tract infections:

Pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, quinsy.

Other infections caused by Flucloxacillin - sensitive organisms:

Osteomyelitis, enteritis, endocarditis, urinary tract infection, meningitis, septicaemia. Flucloxacillin is also indicated for use as a prophylactic agent during major surgical procedures where appropriate; for example, cardiothoracic and orthopaedic surgery.

DOSAGE AND ADMINISTRATION

Doses should be administered at least one hour before meals.

Adult: 250-500 mg four times daily.

Osteomyelitis, endocarditis: Up to 8 g daily in divided doses, six to eight hourly.

Skin and soft tissue infections: Up to 8 g daily in divided doses, six to eight hourly.

Children 2-10 years: 125 mg 4 times daily.

Children 2 months-2 years: 62.5 mg 4 times daily.

Impaired renal function: In common with other Penicillins, Flucloxacillin usage in patients with renal impairment does not usually require dosage reduction. However, in the presence of severe renal failure (creatinine clearance <10 mL/min) a reduction in dose or an extension of dose interval should be considered. Flucloxacillin is not significantly removed by dialysis and hence no supplementary dosages need to be administered either during or at the end of the dialysis period.

CONTRAINDICATION

Hypersensitivity to Penicillin or Cephalosporin. It is contraindicated in patients with a previous history of Flucloxacillin associated jaundice or hepatic dysfunction.

USE IN PREGNANCY AND LACTATION

Use in pregnancy: Safety of **Flucloxin**® in pregnancy has not yet been established.
Use in lactation: **Flucloxin**® is excreted in breast milk. There are no known detrimental effects to the infant.

SIDE-EFFECTS

Side effects, as with other Penicillins, are uncommon and mainly of a mild and transitory nature. Gastrointestinal upsets (e.g. nausea, diarrhoea) and skin rashes have been reported infrequently. If a skin rash occurs, treatment should be discontinued.

OVERDOSAGE

Problems of overdosage with Flucloxacillin are unlikely to occur; if encountered they may be treated symptomatically.

PHARMACEUTICAL PRECAUTION

Flucloxin® capsule and powder for syrup should be kept away from wet place, below 25 ˚C temperature and should be protected from light. Keep out of reach of children.

PACKAGING

Flucloxin® 250 mg capsule: Box containing 10 strips of 10 capsules each. Each capsule contains 250 mg Flucloxacillin as Flucloxacillin Sodium BP.

Flucloxin® 500 mg capsule: Box containing 10 strips of 4 capsules each. Each capsule contains 500 mg Flucloxacillin as Flucloxacillin Sodium BP.

Flucloxin® syrup: Bottle containing powder for the preparation of 100 mL syrup. After reconstitution each 5 mL contains 125 mg Flucloxacillin as Flucloxacillin Sodium BP.

SK+F

Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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