Flux®

Flucloxacillin

Description
Flucloxacillin (**Flux®**) is an isoxazolyl penicillin, which combines the properties of resistance to hydrolysis by penicillinase, gastric acid stability and activity against gram-positive bacteria. Flucloxacillin is a bactericidal antibiotic that is particularly useful against penicillinase producing staphylococci.

Mode of action
Flucloxacillin kills bacteria by interfering in the synthesis of the bacterial cell wall.

Pharmacokinetics
Flucloxacillin is well absorbed following oral administration and the serum concentrations attained are comparable to those achieved following intramuscular administration. Peak serum concentrations are achieved 0.5-1 h after administration. Increasing the dose results in a corresponding increase in the peak serum concentrations of flucloxacillin. The percentage of an oral dose of flucloxacillin excreted unchanged in the urine varies from 40 to 70%. After the intramuscular administration of a single 250 or 500 mg dose of flucloxacillin to volunteers, mean peak concentrations of the drug in serum were approximately 10.5 and 16 mg/L, respectively. Mean urinary excretion of flucloxacillin following its intramuscular use is 61% of the administered dose. Flucloxacillin may also be administered by intravenous bolus injection or by short intravenous infusion. The percentage of a dose of intravenous flucloxacillin recovered in urine in a 8 hrs collection period varies from 60 to 76%. Flucloxacillin is highly bound to serum proteins, with only 5.3% unbound (free). After a 500 mg oral dose, the serum half-life of flucloxacillin in healthy adults has been variously reported as 43 mins, 66 mins and 77.6 mins. Flucloxacillin is excreted mainly in the urine, largely as the unchanged compound (65%). As a consequence, the elimination of the drug is reduced in moderate to severe renal disease. Hepatic disease is unlikely to affect the kinetics of flucloxacillin to any significant extent. Old age does not affect the elimination or flucloxacillin.

Composition
Flux® 250 mg Capsule: Each capsule contains Flucloxacillin Sodium BP 272.05 mg equivalent to Flucloxacillin 250 mg.
Flux® 500 mg Capsule: Each capsule contains Flucloxacillin Sodium BP 544.1 mg equivalent to Flucloxacillin 500 mg.
Flux® Powder for Solution: After reconstitution each 5 ml contains Flucloxacillin Sodium BP 136.03 mg equivalent to Flucloxacillin 125 mg.
Flux® DS Powder for Suspension: After reconstitution each 5 ml contains Flucloxacillin Sodium BP 272.05 mg equivalent to Flucloxacillin 250 mg.
Flux® 250 mg Injection: Each vial contains sterile Flucloxacillin Sodium BP 272.05 mg equivalent to Flucloxacillin 250 mg.
Flux® 500 mg Injection: Each vial contains sterile Flucloxacillin Sodium BP 544.1 mg equivalent to Flucloxacillin 500 mg.

Indications
Flucloxacillin is indicated for the treatment of infections due to gram-positive organisms, including infections caused by ß-lactamase producing staphylococci. Skin and soft tissue infections: Boils, abscesses, carbuncles, furunculosis, cellulitis, infected skin conditions, e.g. ulcer, eczema and acne, 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 cardio-thoracic and orthopaedic surgery.

Dosage & administration
The following recommended dosages are given as a guide. In severe infections they may be increased. Oral doses should be administered 0.5-1 hr before meals. Intravenous administration can be by slow injection (3-4 min) or by short infusion. The usual adult oral dosage is 250 mg four times daily. Intramuscular: 250 mg to 1 gm four times daily. Systemic dosages may be doubled where necessary (upto 8 gm daily), particularly for serious infections such as osteomyelitis, septicaemia and endocarditis. Flux® may be administered by other routes in conjunction with systemic therapy. Intrapleural: 250 mg once daily. By nebulizer: 125-250 mg four times daily. Intra-articular: 250-500 mg once daily. The usual dosage for children of 2-10 years is half of the adult dose and for children under 2 years is quarter of the adult dose. The highest doses of flucloxacillin known to have been used are 12-16 gm and 12-18 gm daily for the treatment of early prosthetic valve endocarditis and meningitis, respectively.

Contraindications
Flucloxacillin is contraindicated in patients with penicillin hypersensitivity.

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

Use in pregnancy & lactation
The use of flucloxacillin in pregnancy should be reserved for cases considered essential by the clinicians. Use of the drug in second and third trimesters may result in the sensitization of the foetus. During lactation, trace quantities of penicillins can be detected in breast milk.

Precautions
History of allergy; renal impairment; false-positive urinary glucose.

Drug interactions
The administration of probenecid with flucloxacillin results in higher serum peak concentrations and prolongs the time that therapeutic concentrations of flucloxacillin are achieved in serum. Physical incompatibility and/or loss of activity of flucloxacillin in solution has been reported when given with gentamycin sulphate. Streptomycin sulphate, vitamin mixture, physical incompatibility of flucloxacillin, upto 72 hrs at 15°C and/or 30°C was reported with atropine sulphate, benzylpenicillin. Chlorpromazine, diazepam, hyoscine butylbromide, isosorbide dinitrate, metoclopramide, tetracycline HCl, prochlorperazine, promethazine, etc.

Storage
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Flux® 250 mg Capsule: Each carton contains 4X7 capsules in strip pack.
Flux® 500 mg Capsule: Each carton contains 4X7 capsules in strip pack.
Flux® Powder for Solution: Each carton contains a bottle having dry powder to reconstitute 100 ml solution.
Flux® DS Powder for Suspension: Each carton contains a bottle having dry powder to reconstitute 100 ml DS suspension.
Flux® 250 mg Injection: Each carton contains 1X4 vials with water for injection in blister pack.
Flux® 500 mg Injection: Each carton contains 1X6 vials with water for injection and 6 disposable syringes in blister pack.

Opsonin
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Ideas for healthcare

Manufactured by
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