

Only for the use of Medical Professionals

Fluclox[®]

Flucloxacillin

Presentation

Fluclox[®] 250mg Capsule: Black cap and caramel body, both body and cap imprinted with either 'FLUCLOX' or 'ACI'. Each capsule contains Flucloxacillin 250mg as Sodium BP.

Fluclox[®] 500mg Capsule: Dark blue cap and light blue body, both body and cap imprinted with either 'FLUCLOX 500' or 'ACI'. Each capsule contains Flucloxacillin 500mg as Sodium BP.

Fluclox[®] Powder for Suspension (125mg/5ml): Bottles containing powder for the preparation of 100ml pink colored, orange flavored suspension; when reconstituted each 5ml contains Flucloxacillin 125mg as Sodium BP.

Fluclox[®] DS Powder for Suspension (250mg/5ml): Bottles containing powder for the preparation of 100ml pink colored, orange and banana flavored suspension; when reconstituted each 5ml contains Flucloxacillin 250mg as Sodium BP.

Fluclox[®] 250mg injection: Vials containing Flucloxacillin 250mg as Sodium BP; presented as powder for reconstitution.

Fluclox[®] 500 mg injection: Vials containing Flucloxacillin 500 mg as Sodium BP; presented as powder for reconstitution.

Uses

Fluclox[®] is indicated for the treatment of infections due to Gram positive organisms, including infections caused by beta-lactamase producing Staphylococci.

Typical indications include:

Skin and soft tissue infections: Boils, abscesses, carbuncles, infected skin conditions, for example, ulcer, eczema, acne, furunculosis, cellulitis, infected wounds, infected burns, protection for skin grafts, otitis media and external impetigo.

Respiratory tract infections: Pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, quinsy.

Other infections caused by Fluclox[®]-sensitive organisms: Osteomyelitis, enteritis, endocarditis, urinary tract infections, meningitis, septicaemia.

Fluclox[®] is also indicated for use as a prophylactic agent during major surgical procedures, where appropriate; for example, cardiothoracic and orthopaedic surgery.

Dosage and administration

Adults (including elderly patients):

Oral : 250-500mg four times daily, and should be administered ½ to 1 hour before meals.

Intramuscular : 250mg four times daily.

Intravenous : 250-500mg four times daily. The above systemic doses may be doubled where necessary.

Osteomyelitis, endocarditis : Up to 8g daily, in divided dosages 6 to 8 hourly.

Surgical prophylaxis : 1 to 2g IV at induction of anaesthesia followed by 500mg six hourly, IV, IM or orally for up to 72 hours.

Fluclox[®] may be administered by other routes in conjunction with systemic therapy.

Intrapleural : 250mg once daily.
Intra-articular : 250-500mg once daily.
By nebuliser : 125-250mg four times daily.

Children:

2-10 years: ½ of the adult dose.

Under 2 years: ¼ of the adult dose.

Children have been given doses of 12.5 to 25 mg per kg body weight four times daily.

Abnormal renal function: In common with other penicillins, Fluclox® usage in patients with renal impairment does not usually require dosage reduction. However, in the presence of severe renal failure (creatinine clearance <10ml/min) a reduction in dose or an extension of dosage interval should be considered.

Fluclox® 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.

Administration:

Intramuscular: Add 1.5ml Water for Injection BP to 250mg vial contents or 2ml Water for Injection BP to 500mg vial contents.

Intravenous: Dissolve 250-500mg in 5-10ml water for Injection BP. Administer by slow intravenous injection (three to four minutes). Fluclox® may also be added to infusion fluids or injected, suitably diluted, into the drip tube over a period of three to four minutes.

Intrapleural: Dissolve 250mg in 5-10ml Water for Injection BP.

Intra-articular: Dissolve 250-500mg in up to 5ml Water for Injection BP or 0.5% Lignocaine hydrochloride solution.

Nebuliser solution: Dissolve 125-250mg of the vial contents in 3ml sterile water.

Contra-indications, warnings, etc.

Contra- indications: Penicillin hypersensitivity; ocular administration.

Use in pregnancy and lactation: Animal studies with Flucloxacillin have shown no teratogenic effect. The use of Flucloxacillin in pregnancy should be reserved for cases considered essential by the clinician. During lactation, trace quantities of penicillins can be detected in breast milk.

Side effects: Side effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature, gastrointestinal upsets (e.g. nausea, diarrhea) and skin rashes have been reported. If a skin rash occurs, treatment should be discontinued. Hepatitis and cholestatic jaundice have been reported rarely. Pseudomembranous colitis has been reported rarely and has usually been associated with use of Flucloxacillin in combination with other antibiotics.

Over dosage: Problems of over dosage with Flucloxacillin are unlikely to occur; if encountered they may be treated symptomatically.

Pharmaceuticals precautions

Store in a cool, dry place, protected from light.

Fluclox® DS, Powder for Suspension should be freshly prepared. Prepared suspension is to be consumed within 7 days of preparation if kept in room temperature or within 14 days if kept in a refrigerator.

Solutions for IM or direct IV injection should normally be administered within 30 minutes of preparation. However, aqueous solutions of Fluclox®, injections retain their activity for up to

24 hours at room temperature (25° C) and up to 72 hours in a refrigerator (5° C). Fluclox® may be added to most intravenous fluids (e.g. water for Injections, sodium chloride 0.9%, glucose 5%, sodium chloride 0.18% with glucose 4%); Intravenous solutions of Fluclox® for infusion, stored up to 25° C, should be used within 24 hours of preparation. Reconstitution of Fluclox® Injections and preparation of Fluclox® infusion solutions must be carried out under appropriate conditions if the extended storage periods are required. Fluclox® should not be mixed with blood products or other proteinaceous fluids (e.g. protein hydrolysates) or with intravenous lipid emulsions. If Fluclox® is prescribed concurrently with an aminoglycoside, the two antibiotics should not be mixed in the syringe, intravenous fluid container or giving set; precipitation may occur.

Package quantities

Fluclox® 250mg Capsule: Carton of 100 capsules in aluminium strips.

Fluclox® 500mg Capsule: Carton of 40 capsules in aluminium strips.

Fluclox® Powder for Suspension (125mg/5ml): Bottle of 100ml.

Fluclox® DS Powder for Suspension (250mg/5ml): Bottles of 100ml.

Fluclox® 250mg injection: Box containing 1vial of 250mg Flucloxacillin and 1 ampoule of 5ml water for Injection BP for dilution.

Fluclox® 500mg injection: Box containing 1 vial of 500mg Flucloxacillin and 1 ampoule of 5ml water for Injection BP for dilution.

Manufactured by



ACI Limited

Narayanganj, Bangladesh.