Flucloxin®

Flucloxacillin Capsule, Powder for Syrup & Powder for IV/IM Injection

DESCRIPTION

Flucloxin® is a preparation of Flucloxacillin. Flucloxacillin is a Beta-lactamase resistant penicillin. Flucloxacillin is bactericidal with a similar mode of action to benzylpenicillin. It is resistant to staphylococcal penicillinase and therefore active against penicillinase producing and non-penicillinase-producing staphylococci. Its activity against streptococci such as *Streptococcus pneumoniae* and *Str. Pyogenes* is less than that of benzylpenicillin but sufficient to be useful when these organisms are present with penicillin-resistant staphylococci. It is virtually ineffective against *Enterococcus faecalis*.

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, Impetigo, infected burns, infected wounds, protection for skin grafts, Otitis Media and Externa.
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 & ADMINISTRATION

Oral Administration: Doses should be administered at least one hour before meals.
Adults: 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.

Paediatric population:
Children 2-10 years: 125 mg 4 times daily.
Children 2 months-2 years: 62.5 mg 4 times daily

- **Dosage in patients with impaired liver function:** Adjustment of dosage may not be necessary as Flucloxacillin is not metabolized in the liver to any appreciable extent. However, during prolonged treatment it is advisable to check periodically for hepatic dysfunction.

- **Dosage in patients with impaired renal function:** As Flucloxacillin is excreted to a large extent by the kidney, the dose or dose interval may need modification in patients with renal failure.

Parenteral Administration:

Adults and Elderly:

Intramuscular: Dissolve 500 mg vial content in 2 mL of water for injection.

Intravenous: Dissolve 500 mg vial content in 5 mL of water for injection and administer by slow intravenous injection (over three to four minutes). Flucloxacillin may be added to most intravenous fluids (eg water for injection, sodium chloride 0.9%, glucose 5%, sodium chloride 0.18% with glucose 4%). Flucloxacillin may also be added to infusion fluids or injected (suitably diluted) into the drip tube over three to four minutes.

Intra-articular: Dissolve 250 to 500 mg vial content in up to 5 mL of water for injection.

Surgical Prophylaxis: During surgical prophylaxis, doses of 1 to 2 g should be given intravenously at induction of anaesthesia followed by 500 mg six hourly intravenously or intramuscularly.

Paediatric population:

Any route of administration may be used. For children under two years old, a quarter of the adult dose should be administered. For children two to ten years old, half of the adult dose should be administered.

CONTRAINDICATIONS

- Hypersensitivity to Penicillin
- Flucloxacillin is contraindicated in patients with a previous history of Flucloxacillin associated jaundice/hepatic dysfunction.

SIDE EFFECTS

- Diarrhea/loose stools
- Nausea and vomiting
- Skin rashes and urticaria
- Thrombocytopenia

OVERDOSAGE

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

PRECAUTION & WARNING

Flucloxacillin can cause severe hepatitis and cholestatic jaundice, which may be protracted. This reaction is more frequent in older patients and those who take the drug for prolonged periods. Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including Flucloxacillin. Hepatitis, predominantly of a cholestatic type, has been reported.

USE IN PREGNANCY & LACTATION

Pregnancy: There has been no evidence of a teratogenic effect in animals or untoward effect in humans. However, use in pregnancy should be reserved for essential cases.

Breastfeeding: Trace quantities of penicillin can be detected in breast milk with the potential for hypersensitivity reactions (e.g. drug rashes) in the breast-fed neonate.

PHARMACEUTICAL PRECAUTION

For Capsule, Powder for Syrup & Injection: Keep away from light & wet place. Do not store above 25°C temperature.

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® Powder for syrup: Bottle containing powder for the preparation of 100 mL syrup. After reconstitution each 5 mL contains 125 mg Flucloxacillin as Flucloxacillin Sodium BP.
Flucloxin® 500 IV/IM Injection: Box containing 1 vial & 1 ampoule. Each Vial Contains Flucloxacillin Sodium for Injection BP equivalent to Flucloxacillin 500 mg. Each ampoule contains Water for Injection USP 5 mL for reconstitution.

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Manufactured by
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