FLUBION

Flucloxacillin BP

500 mg Capsule

COMPOSITION

FLUBION Capsule: Each capsule contains Flucloxacillin Sodium BP equivalent to 500 mg Flucloxacillin.

PHARMACOLOGY

FLUBION (Flucloxacillin) is an antibiotic of penicillinase-resistant penicillin group. Flucloxacillin is bactericidal with a mode of action similar to that of benzylpenicillin but active against both penicillinase-producing and non-penicillinase-producing staphylococci. Flucloxacillin is better absorbed than cloxacillin but absorption is reduced by the presence of food in the stomach. Half-life of Flucloxacillin is approximately 1 hour, prolonged in neonates; about 95% of Flucloxacillin is bound to plasma proteins, about 66% of a dose is excreted in urine within 8 hours.

INDICATIONS

FLUBION (Flucloxacillin) is used primarily for the treatment of infections due to staphylococci resistant to benzylpenicillin, like

- Skin and soft tissue infections: boil, carbuncles, abscesses, infected skin conditions (ulcer, eczema, and acne) furunculosis, cellulitis, infected wounds, infected burns, otitis media, external impetigo and protection for skin grafts
- Respiratory tract infections: pneumonia, lung abscess, emphema, sinusitis, pharyngitis, tonsillitis, quinsy
- Bone and joint infections : osteomyelitis
- Other infections caused by Flucloxacillin sensitive organism: enteritis, endocarditis, urinary tract infections, meningitis, septicaemia
- As a prophylactic agents during major surgical procedures where appropriate Cardiothoracic & Orthopedic surgery

DOSAGE AND ADMINISTRATION

Dose should be individualized, depending on patient's conditions and response. **FLUBION** (Flucloxacillin) should be administered at least 30 minutes before meal.

Adults: 250 mg - 500 mg every 6 hours.

Children: Under 2 years: 62.5 mg -125 mg every 6 hours.

2-10 years: 125 mg - 250 mg (every 6 hours.

In endocarditis: Body weight under 85 kg: Up to 8 gm daily in 3-4 divided doses.

Body weight over 85 kg : up to 12 gm in 6 divided doses. In osteomyelitis : Up to 8 gm daily in 3-4 divided doses.

In renal impairment: Dose or dose interval may need adjustment. In hepatic impairment: Adjustment of dosage may not be necessary.

CONTRAINDICATIONS

FLUBION is contraindicated in known hypersensitivity to Flucloxacillin or Penicillin.

PRECAUTIONS

Flucloxacillin should be used with caution in hepatic impairment, renal impairment, allergic diathesis, history of colitis. Flucloxacillin can cause severe hepatitis and cholestatic jaundice, more frequent in older patients and those who take the drug for prolong period. Like other antibiotics, pseudomembranous colitis has been reported.

IN PREGNANCY AND LACTATION

In pregnancy: Pregnancy category B. Not known to be harmful nevertheless should be used during pregnancy only if clearly needed.

In lactation: Flucloxacillin is excreted in breast milk in trace amounts. So, it should be used with caution in nursing mothers and only if the expected benefit to the mother is greater than the possible risk to the nursing infant.

SIDE EFFECTS

Gastro-intestinal: Nausea, vomiting, diarrhoea and dyspepsia, Hypersensitivity reactions: Erythematous, maculopapular rashes, urticaria, purpura, cosinophilia, angioneurotic oedema, anaphylaxis and erythema multiforme. Renal: Isolated cases of nephritis and haematuria. Liver: Hepatitis and cholestatic jaundice. And Haemic and lymphatic systems: anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leucopenia, neutropenia and agranulocytosis.

DRUG INTERACTIONS

Probenecid: excretion of Flucloxacillin is reduced, results in increased plasma concentration. Aminoglycosides (Gentamycin sulphate, Streptomycin sulphate): loss of Flucloxacillin activity.

STORAGE CONDITIONS

Store below $30^{\circ}\mathrm{C}$ temperature, dry place and away from light. Keep all medicine out of the reach of children.

HOW SUPPLIED

FLUBION-500 Capsule: Each Box containing 7x4's capsule in Alu-Alu Blister packs.

