Phylopen®

Flucloxacillin

COMPOSITION

Phylopen® 250 Capsule: Each capsule contains Flucloxacillin 250 mg (as Flucloxacillin Sodium BP).
Phylopen® DS Capsule: Each capsule contains Flucloxacillin 500 mg (as Flucloxacillin Sodium BP).
Phylopen® Powder for Suspension: After reconstitution each 5 ml contains Flucloxacillin 125 mg (as Flucloxacillin Sodium BP).
Phylopen® Forte Powder for Suspension: After reconstitution each 5 ml contains Flucloxacillin 250 mg (as Flucloxacillin Sodium BP).
Phylopen® 500 IM/IV injection: Each vial contains Flucloxacillin 500 mg (as Flucloxacillin Sodium BP).

PHARMACOLOGY

Flucloxacillin is an isoxazolyl penicillin of the β-lactam group of antibiotics which exerts a bactericidal effect upon many Gram-positive organisms including β-lactamase-producing *staphylococci* and *streptococci*. It is not active against methicillin-resistant *staphylococci*.

INDICATION

Flucloxacillin is indicated for the treatment of infections due to Gram-positive organisms, including infections caused by β-lactamase producing *staphylococci*.

Typical indications include:
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, impetigo.
Respiratory tract infections: pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, quinsy, otitis media and externa.
Other infection 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

Oral administration:

Oral doses should be administered half to one hour before meals.
Usual adult dosage (including elderly patients): 250 mg four times daily. *In severe infections:* dosage should be doubled. *In osteomyelitis and endocarditis:* upto 8 g daily, in divided doses 6 to 8 hourly.
In case of secondary bacterial infection in chicken pox: Flucloxacillin 500 mg 6 hourly should be prescribed.
Usual children dosage:
2-10 years: half of the adult dose. Under 2 years: quarter of the adult dose.

Parenteral Administration:

Usual adult dosage (including elderly patients)

Intramuscular injection: 250 mg four times daily. *Intravenous injection:* 250 mg to 1 gm 4 times daily by slow injection over 3 to 4 minutes or by intravenous infusion.

All systemic doses may be doubled in severe infections: doses up to 8 gm daily have been suggested for endocarditis or osteomyelitis. Flucloxacillin has been used in other routes in conjunction with other therapy. It has been administered in a dose of 250 mg to 500 mg daily by intraarticular injection, dissolved if necessary in a 0.5% solution of lidocaine hydrochloride and by intrapleural injection in dose of 250 mg daily. Using powder for injection, 125 mg to 250 mg has been dissolved in 3 ml of sterile water and inhaled by nebuliser four times daily.

Usual children dosage:
2-10 years: half of the adult dose. Under 2 years: quarter of the adult dose

Dosage adjustment in renal impairment:
As 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 dosage needs to be administered either during or at the end of the dialysis period.

CONTRAINDICATION

Penicillin hypersensitivity.

SIDE EFFECT

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

DRUG INTERACTION

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 have been reported when given with gentamicin sulphate, streptomycin sulphate and vitamin mixtures.
Flucloxacillin should not be added to intravenous lipids, blood products and protein hydrolysates or other proteinaceous fluids.

USE IN PREGNANCY & LACTATION

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

STORAGE

Store in a cool (below 25^0 C.), dry place. Protect from light and moisture.

HOW SUPPLIED

Phylopen® 250 Capsule: Each box contains 100 capsules in alu-alu blister pack.
Phylopen® DS Capsule: Each box contains 42 capsules in alu-alu blister pack.
Phylopen® Powder for Suspension: Each bottle contains dry powder to make 100 ml suspension.
Phylopen® Forte Powder for Suspension: Each bottle contains dry powder to make 100 ml suspension.
Phylopen® 500 IM/IV injection: Each box contains 5 blister packs, each containing one vial and one 5 ml ampoule of Water For Injection BP.

Manufactured by
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