Phylopen®

Flucloxacillin

Medium & Narrow Spectrum Penicillin

COMPOSITION

Phylopen® 250 capsule : Each capsule contains Flucloxacillin BP 250 mg (as Flucloxacillin Sodium BP).

Phylopen® DS capsule : Each capsule contains Flucloxacillin BP 500 mg (as Flucloxacillin Sodium BP).

Phylopen® dry syrup : Each 5 ml contains Flucloxacillin BP 125 mg (as Flucloxacillin Sodium BP).

Phylopen® Forte syrup : Each 5 ml contains Flucloxacillin BP 250 mg (as Flucloxacillin Sodium BP).

Phylopen® 250 injection: Each vial contains Flucloxacillin BP 250 mg (as Flucloxacillin Sodium BP).

Phylopen® 500 injection: Each vial contains Flucloxacillin BP 500 mg (as Flucloxacillin Sodium BP).

PHARMACOLOGY

Flucloxacillin is isoxazolyl penicillin which combined 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. Flucloxacillin kills bacterial cellwall, thus interfering with peptidoglycan synthesis. Peptidoglycan is a heteropolymeric structure that provides the cell wall with its mechanical stability. The final stage of peptidoglycan synthesis involves the completion of the cross-linking with the terminal glycine residue of the pentaglycin bridge linking to the fourth residue of the pentapeptide (D-alanine). The transpeptidase enzyme that performs this step is inhibited by Flucloxacillin. As a result the bacterial cellwall is weakened, the cell swells and then ruptures. Flucloxacillin resists the action of bacterial penicillinase probably because of the steric hindrance induced by the acyl side chain which prevents the opening of the β-lactam ring.

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, otitis media and externa, impetigo.

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

Other infections caused by Flucloxacillin-sensitive organisms: osteomyelitis, enteritis, endocarditis, urinary tract infections, 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: up to 8 gm daily, in divided doses 6 to 8 hourly.

In case of secondary bacterial infection in chicken pox: Flucloxacillin 500 mg six 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-1 g four 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 g daily have been suggested for endocarditis or osteomyelitis.

Flucloxacillin has been used in other routes in conjunction with systemic 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 lignocaine hydrochloride, and by intrapleural injection in a dose of 250 mg daily. Using powder for injection, 125 mg - 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.

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

USE IN PREGNANCY AND 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 sensitisation of the fetus. During lactation, trace quantities of penicillins can be detected in breast milk.

STORAGE CONDITION
Store in a cool and dry place. Protect from light and moisture.

Phylopen®

HOW SUPPLIED

Phylopen® 250 capsule : Box containing 5 x 10 capsules in strip pack.

Phylopen® DS capsule : Box containing 5 x 6 capsules in alu-alu blister pack.

Phylopen® dry syrup : Bottle containing dry powder for reconstitution to 100 ml syrup.

Phylopen® Forte syrup : Bottle containing dry powder for reconstitution to 100 ml syrup.

Phylopen® 250 injection: Box containing 5 blister packs, each containing one vial of Phylopen® 250 injection and one 5 ml ampoule of Water for Injection.

Phylopen® 500 injection: Box containing 5 blister packs, each containing one vial of Phylopen® 500 injection and one 5 ml ampoule of Water for Injection.