Sinaflox

Flucloxacillin

Composition:

Sinaflox 250 Capsule: Each capsule contains Flucloxacillin BP 250 mg (as Flucloxacillin sodium BP). **Sinaflox** 500 Capsule : Each capsule contains Flucloxacillin BP 500 mg (as Flucloxacillin sodium BP). **Sinaflox** Suspension: After reconstitution each 5 ml contains Flucloxacillin BP 125 mg (as Flucloxacillin sodium BP).

Description:

Sinaflox covalently binds to a heterologous group of proteins called penicillin-binding proteins (PBPs); These PBPs may number 3 to 6 in any given bacteria. Their functions are diverse: catalyze the transpeptidase reaction; maintain shape, forms septum during division, inhibit autolysis enzymes. Binding to PBPs results in: i). Inhibition of transpeptidase: Transpeptidase catalyzes the cross-linking of the fourth residue (D-Ala) of the pentapeptide. The fifth residue (also D-Ala) is released during this reaction. Spheroblasts are formed. ii). Structural irregularities: Binding to PBPs may result in abnormal elongation, abnormal shape, cell wall defects. iii). Activation of autolytic enzymes: Binding to PBPs results in disinhibition (i.e. activation) of autolytic enzymes.

Indication:

Sinaflox is indicated for the treatment of infections due to gram-positive organisms, including infections caused by ß-lactamase producing staphylococci. Typical indications include - *Skin & soft tissue infections:* Boils (furuncle or furunculosis), abscesses, carbuncles, cellulitis; infected skin conditions e.g. ulcer, eczema, acne, infected wounds, infected burns, protection for skin grafts, otitis media and externa, impetigo. *Respiratory tract infections:* Pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis. Other infection caused by Flucloxacillin-sensitive organisms: Osteomyelitis, enteritis, endocarditis, urinary tract infection, meningitis, septicemia. **Sinaflox** 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 doses should be administered half to one hour before meals. ***Adults*** *(including elderly patients):* 250 mg four times daily. *In severe infections:* Dosage should be doubled. *Osteomyelitis, endocarditis:* Up to 8 gm daily, in divided doses 6 to 8 hourly. *In case of secondary bacterial infection in chicken pox:* 500 mg six hourly. ***Usual children dosage 2-10 years:*** Half of the adult dose. ***Under 2 years:*** Quarter of the adult dose. *Abnormal renal function:* In common with other penicillins, **Sinaflox** 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. **Sinaflox** 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.

Pharmacokinetic properties:

Absorption: Flucloxacillin is stable in acid media and can therefore be administered either by the oral or parenteral route. The peak serum levels of Flucloxacillin reached after one hour are as follows. After 250 mg by the oral route: Approximately 8.8 mg/lit. After 500 mg by the oral route: Approximately 14.5 mg/lit. After 500 mg by the IM route: Approximately 16.5 mg/lit. The total quantity absorbed by the oral route represents approximately 79% of the quantity administered. ***Distribution:*** Flucloxacillin diffuses well into most tissue. Specifically active concentrations of Flucloxacillin have been recovered in bones:

11.6 mg/lit. (compact bone) and 15.6 mg/lit. (spongy bone), with a mean serum level of 8.9 mg/lit. ***Metabolism:*** In normal subjects approximately 10% of the Flucloxacillin administered is metabolized to penicilloic acid. The elimination half-life of Flucloxacillin is in the order of 53 minutes. ***Excretion:*** Excretion occurs mainly through the kidney. Between 65.5% (oral route) and 76.1% (parenteral route) of the dose administered is recovered in unaltered active form in the urine within 8 hours. A small portion of the dose administered is excreted in the bile. The excretion of Flucloxacillin is slowed in cases of renal failure. Protein binding: The serum protein-binding rate is 95%.

Contraindication:

Hypersensitivity to penicillins.

Side effect:

Side effects like other penicillins are uncommon and mainly of a mild and transitory nature. Gastrointestinal upsets (e.g. nausea, diarrhoea) and skin rashes have been reported. If a skin rash occurs, treatment should be discontinued.

Drug interaction:

The concurrent administration of probenecid and Flucloxacillin results in higher serum peak concentrations and prolongs the time that therapeutic concentrations of Flucloxacillin are achieved in serum.

Use in pregnancy & lactation:

Pregnancy: Animal studies with Flucloxacillin have shown no teratogenic effects. The product has been in clinical use since 1970 and the limited numbers of reported cases of use in human pregnancy have shown no evidence of untoward effects. The decision to administer any drug during pregnancy should be taken with the utmost care. Therefore Flucloxacillin should only be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment. ***Lactation:*** Trace quantities of Flucloxacillin can be detected in breast milk. The possibility of hypersensitivity reactions must be considered in breast-feeding infants. Therefore Flucloxacillin should only be administered to a breast-feeding mother when the potential benefits outweigh the potential risks associated with the treatment.

Presentation:

Sinaflox 250 Capsule: Each box containing 5 x 10 capsules in alu-alu blister pack.
Sinaflox 500 Capsule: Each box containing 5 x 10 capsules in alu-alu blister pack.
Sinaflox Suspension: Bottle containing dry powder for 100 ml oral suspension.

Manufactured by:

IBN SINA
The IBN SINA Pharmaceutical Industry Ltd.
Shafipur, Kliakoir, Gazipur, Bangladesh.