

Halopen

Flucloxacillin

COMPOSITION

Halopen 250 Capsule: Each capsule contains Flucloxacillin Sodium BP equivalent to Flucloxacillin 250 mg.

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

Halopen Powder for Suspension: After reconstitution, each 5 ml suspension contains Flucloxacillin Sodium BP equivalent to Flucloxacillin 125 mg.

PHARMACOLOGY

Halopen is a preparation of Flucloxacillin. It is active against Gram-positive organisms including penicillinase producing strains. It has little activity against Gram-negative bacilli. Flucloxacillin acts by inhibiting the formation of cell wall of bacteria.

INDICATIONS

Flucloxacillin is indicated for the treatment of infections due to Gram-positive organisms, including infections caused by penicillinase producing *staphylococci*. These indications include:

Skin and soft tissue infections: Boils, abscess, carbuncles, infected skin conditions (e.g. ulcer, eczema, acne, furunculosis, cellulitis, infected wounds, infected burns, otitis media and externa, impetigo).

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

It is also used for the treatment of other infections i.e. osteomyelitis, enteritis, endocarditis, urinary tract infection, meningitis, septicaemia caused by Flucloxacillin-sensitive organisms.

As a prophylactic agent, it is used during major surgical procedures where appropriate; for example, cardiothoracic and orthopedic surgery.

DOSAGE AND ADMINISTRATION

Adult: 250 mg four times daily. Dosage may be doubled in severe infections. In osteomyelitis and endocarditis, up to 8g daily is used in 6-8 hourly divided doses.

Children (2-10 years): $\frac{1}{2}$ of adult dose.

Children (Under 2 years): $\frac{1}{4}$ th of adult dose.

In severe renal failure (creatinine clearance <10 ml/min), a reduction in dose or an extension of dose interval should be considered.

Oral doses should be administered 1 hour before meal.

CONTRAINDICATIONS

Flucloxacillin is contraindicated in penicillin hypersensitive patients.

WARNING & PRECAUTION

Flucloxacillin should be used with caution in patients with evidence of hepatic dysfunction. Caution should also be exercised in the treatment of patients with an allergic diathesis.

SIDE EFFECTS

There have been some common side effects of gastrointestinal tract such as nausea, vomiting, diarrhoea, dyspepsia and other minor gastrointestinal disturbances. Besides these rashes, urticaria, purpura, fever, interstitial nephritis, hepatitis and cholestatic jaundice have been reported.

USE IN PREGNANCY & LACTATION

US FDA Pregnancy Category of Flucloxacillin is B. There are, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Flucloxacillin has been shown to be excreted in human milk. So, caution should be exercised when Flucloxacillin is administered to a lactating mother.

USE IN CHILDREN & ADOLESCENTS

Can be given less than 2 years of age.

DRUG INTERACTIONS

Concurrent use of Flucloxacillin and Probenecid may result in increased level of Flucloxacillin in blood for prolonged period.

OVERDOSAGE

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident. With high parenteral doses neurotoxicity (e.g. convulsions, encephalopathy), blood disorders (e.g. neutropenia, haemolytic anaemia, prolongation of bleeding time, defective platelet function) or electrolyte disturbances may occur. Flucloxacillin is not removed from the circulation by haemodialysis. Treatment is symptomatic.

STORAGE

Capsule: Store below 30°C temperature in a cool & dry place. Protect from light & moisture.

Powder for Suspension: Store below 25°C temperature in a cool & dry place. Protect from light & moisture.

Keep out of the reach of children.

HOW SUPPLIED

Halopen 250 Capsule: Each box contains 40 capsules in Alu-Alu blister pack.

Halopen 500 Capsule: Each box contains 28 capsules in Alu-Alu blister pack.

Halopen Powder for Suspension: Each amber glass bottle contains dry powder to reconstitute 100 ml suspension.