SPMC

Flucloxacillin Capsule BP 250 mg

Flucloxacillin Capsules BP 500 mg

1. Pharmacological Properties and Therapeutic Indications of Flucloxacillin Capsules

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.

Therapeutic Indications:

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, Sinusitis, Tonsillitis, Lung abscess, Pharyngitis, Quinsy, Empyema, Otitis media and externa

Other infections caused by flucloxacillin-sensitive organisms: Osteomyelitis, Enteritis, Endocarditis, Urinary tract infection, Meningitis, Septicaemia

Flucloxacillin capsules is also indicated for use as a prophylactic agent during major surgical procedures when appropriate; for example, cardiothoracic and orthopaedic surgery. Parenteral usage is indicated where oral dosage is inappropriate. Consideration should be given to official local guidance (e.g. national recommendations) on the appropriate use of antibacterial agents. Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

1. Contraindications, Warnings and precautions & Drug Interactions

Contraindications

- Documented hypersensitivity to flucloxacillin, penicillins, or any excipient contained in the formulation (see Section 6).
- A history of flucloxacillin-associated hepatic dysfunction, including cholestatic jaundice.
- Previous hypersensitivity reactions to β-lactam antibiotics, including penicillins and cephalosporins.

Warnings and precautions

- Have renal impairment, as dose adjustment may be required; high doses in patients with significantly reduced renal function have been associated with a rare risk of convulsions.
- Have pre-existing hepatic impairment, as flucloxacillin may exacerbate underlying liver dysfunction.
- Are aged ≥50 years.
- Have significant concomitant systemic illnesses in addition to the infection being treated.
- Require prolonged therapy, in which case periodic monitoring of hepatic and renal function is recommended.
- Are known carriers of the HLA-B*5701 allele.
- Are following a sodium-restricted diet, due to the sodium content of the formulation.
- Are neonates, for whom administration requires particular caution and appropriate clinical monitoring.
- Are concomitantly receiving, or intend to receive, paracetamol, owing to the potential risk of metabolic complications requiring clinical vigilance.

There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis), which occurs when plasma acidity increases, when flucloxacillin is used concomitantly with paracetamol, particularly in certain groups of patients at risk, e.g., patients with severe renal impairment, sepsis, or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease requiring urgent treatment.

The use of flucloxacillin, especially in high doses, may reduce potassium levels in the blood (hypokalaemia). During high-dose flucloxacillin therapy, periodic monitoring of serum potassium concentrations is recommended due to the risk of hypokalaemia.

Drug Interactions

- probenecid or sulfinpyrazone (used to treat gout)
- methotrexate (a chemotherapy drug)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used with general anaesthetics)
- piperacillin (an antibiotic administered by injection)
- warfarin (medicine used to prevent blood clotting)
- paracetamol
- other antibiotics (used to treat infections)
- voriconazole (used against fungal infections).

Pregnancy, breast-feeding, and fertility

The use of flucloxacillin during pregnancy and lactation, in patients who are suspected to be pregnant or planning pregnancy, should be based on a careful assessment of the benefit–risk profile prior to initiation of therapy.

Tests

Regular monitoring of hepatic and renal function is recommended during treatment with flucloxacillin, particularly in cases of prolonged therapy.

Flucloxacillin may interfere with the results of certain laboratory investigations; therefore, patients should be identified as receiving flucloxacillin prior to blood or urine testing.

Flucloxacillin Capsules contain sodium

This medicine contains 48 mg sodium (main component of cooking/table salt) per gram. This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

2. Posology & Method of Administration

2.1. Posology

The dosage depends on the age, weight and renal function of the patient, as well as the severity of the infection.

Adults (including elderly patients)

Oral - 250 mg four times a day. In serious infections, the dosage may be doubled. Osteomyelitis, endocarditis - Up to 8 g daily, in divided doses six to eight hourly. Surgical prophylaxis - 1 to 2 g IV at induction of anesthesia followed by 500 mg six hourly IV, IM or orally for up to 72 hours.

Pediatric population

2-10 years: 125 mg four times daily.

Under 2 years: 62.5mg four times daily.

Premature infants, neonates, suckling's and infants

Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

Abnormal renal function:

In common with other penicillin's, 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. The maximum recommended dose in adults is 1 g every 8 to 12 hours.

Hepatic impairment

Dose reduction in patients with reduced hepatic function is not necessary.

2.2. Method of administration

Oral: This medicine should be taken on an empty stomach. Flucloxacillin capsules should be taken at least 1 hour before or 2 hours after meals. The capsules should be taken with a full glass of water (250 ml), to reduce the risk of esophageal pain. Patients should be advised to remain in an upright position after administration and avoid lying down immediately following ingestion. Adherence to the prescribed dosing schedule is essential to ensure therapeutic efficacy.

Overdose, Missed Dose, and Discontinuation

Overdose

In the event of ingestion of a large number of capsules, or suspected ingestion in a child, immediate medical attention should be sought by contacting the nearest hospital emergency department or a physician. Clinical features of overdose may include nausea, vomiting, and diarrhoea.

Missed Dose

If a dose is missed, it should be taken as soon as it is remembered. However, if it is nearly time for the next scheduled dose, the missed dose should be omitted. A double dose must not be taken to compensate. An interval of approximately 4 hours should be maintained before the next dose is administered.

Discontinuation of Therapy

Premature discontinuation of treatment is not recommended, as incomplete eradication of susceptible organisms may result in relapse or recurrence of infection.

4. Side effects

- hypersensitivity or severe allergic reaction, including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat, or tongue, or breathing problems
- severe bloody diarrhoea (pseudomembranous colitis)
- jaundice (yellowing of the skin and whites of the eyes), hepatitis (liver inflammation) - these liver effects may be delayed for up to 2 months after finishing treatment
- severe skin rash with flushing, fever, blisters, or ulcers (Stevens–Johnson syndrome)
- severe rash with reddening, peeling, and swelling of the skin resembling burns (toxic epidermal necrolysis)
- red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)
- changes in blood cell counts (causing unexplained bleeding, bruising, or skin discolouration).

Common (may affect up to 1 in 10 people):

- minor stomach disturbances, e.g., stomach upset or diarrhoea

Very rare (may affect up to 1 in 10,000 people):

- inflammation of the kidney
- anaemia
- skin rash with circular, red patches (Erythema multiforme)
- joint or muscle pain or fever, which may develop after 2 days or more from the start of treatment with Flucloxacillin capsules
- very rare cases of blood and fluid abnormality (high anion gap metabolic acidosis), which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, generally in the presence of risk factors (see section 2).

Some of these reactions can be delayed for up to two months after finishing treatment.

Not known (frequency cannot be estimated from available data)

- serious skin reactions: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).
- hypokalaemia which can cause muscle weakness, twitching, or abnormal heart rhythm
- pain in the oesophagus and other related symptoms, such as difficulty swallowing, heartburn, throat irritation, or chest pain

Reporting of suspected adverse reactions

Suspected adverse reactions should be reported to the NMRA through the national pharmacovigilance reporting system. Furthermore, suspected adverse reactions should be reported via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

5. Storage Conditions of Flucloxacillin capsules

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package. Shelf life: 24 months. Do not use this medicinal product after the expiry date stated on the carton and blister following "EXP". The expiry date refers to the last day of the stated month.

Medicinal products should not be disposed of via wastewater or household waste. Pharmacist advice should be sought regarding appropriate disposal of unused or expired medicines. These measures are intended to minimize environmental contamination.

6. Contents of the pack and other information

Flucloxacillin contains

The active substance is flucloxacillin sodium.

The other excipients are dried maize starch and magnesium stearate.

Flucloxacillin capsules look like and contents of the pack:

Flucloxacillin 250 mg capsules,

Hard gelatine capsule, size "1", Orange opaque Cap with SPMC logo printed circular rectified in white edible ink & White opaque Body printed with "SPMC" letters circular rectified in black edible ink, containing off-white granules

Available in bulk packs of 100 tablets in HDPE bottles with induction seal, and in Alu/Alu blister packs of 10 × 10 tablets.

Flucloxacillin 500 mg capsules,

Hard gelatine capsule, size "0", Light Blue opaque Cap with SPMC logo printed circular rectified in Black edible ink & White Opaque Body printed with "SPMC" letters circular rectified in black edible ink, containing off-white granules.

Available in bulk packs of 100 tablets in HDPE bottles with induction seal, and in Alu/Alu blister packs of 10 × 10 tablets.

Marketing Authorization Holder and Manufacturer

State Pharmaceuticals manufacturing Corporation
No 11, Sir John Kotelawala Mw, Kandawala Estate, Ratmalana.

Tel. 0112637574. Fax.0112634771
Web: www.spmc.gov.lk

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