



**SPMC
FLUCLOXACILLIN CAPSULES BP 500 mg**

Presentation

100'S capsules bulk pack. light Blue / White capsule "SPMC" logo and "SPMC" letters on the body and cap, each capsule contains 500 mg of Flucloxacillin as flucloxacillin sodium BP.

**SPMC
FLUCLOXACILLIN CAPSULES BP 250 mg**

Presentation

100'S capsules bulk pack & 100 capsules (10X10) blister pack. Orange /White capsule "SPMC" logo and "SPMC" letters on the body and cap, each capsule contains 250 mg of Flucloxacillin as flucloxacillin sodium BP.

INDICATIONS AND DOSE

Infections due to beta-lactamase-producing staphylococci including otitis externa | Adjunct in pneumonia |

Adjunct in impetigo Adjunct in cellulitis

Child 1 month–1 year: 62.5–125 mg 4 times a day

Child 2–9 years: 125–250 mg 4 times a day

Child 10–17 years: 250–500 mg 4 times a day

Adult: 250–500 mg 4 times a day

Surgical prophylaxis

Adult: 1–2 g, to be administered up to 30 minutes before the procedure, then (by mouth or by intramuscular injection or by slow intravenous injection or by intravenous infusion) 500 mg every 6 hours if required for up to 4 further doses in high-risk procedures Staphylococcal lung

infection in cystic fibrosis

Child: 25 mg/kg 4 times a day (max. per dose 1 g), alternatively 100 mg/kg daily in 3 divided doses; maximum 4 g per day.

Prevention of Staphylococcus aureus lung infection in cystic fibrosis—primary prevention

Child 1 month–3 years: 125 mg twice daily

Prevention of Staphylococcus aureus lung infection in cystic fibrosis—secondary prevention

Child: 50 mg/kg twice daily (max. per dose 1 g twice daily)

IMPORTANT SAFETY INFORMATION:

HEPATIC DISORDERS

Cholestatic jaundice and hepatitis may occur very rarely, up to two months after treatment with flucloxacillin has been stopped. Administration for more than 2 weeks and increasing age are risk factors. Healthcare professionals are reminded that:

- flucloxacillin should not be used in patients with a history of hepatic dysfunction associated with flucloxacillin
- flucloxacillin should be used with caution in patients with hepatic impairment
- careful enquiry should be made about hypersensitivity reactions to beta-lactam antibacterial

SPECIAL PRECAUTION:

Patient with spirochaete infections (e.g., syphilis, leptospirosis), history of hypersensitivity to β -lactam antibiotics. Newborn infants. Hepatic or renal impairment. Pregnancy and lactation.

CAUTIONS:

With intravenous use accumulation of

electrolytes can occur with high doses

SIDE EFFECT:

GENERAL SIDE-EFFECTS

Rare or very rare Arthralgia. fever

SPECIFIC SIDE-EFFECTS

Common or very common

With oral use Gastrointestinal disorder

Rare or very rare

With oral use Eosinophilia. myalgia

Frequency not known

With parenteral use Bronchospasm. coma. dyspnea. electrolyte imbalance. erythema nodosum. hallucination. Jarisch Herxheimer reaction. nephropathy. Neurotoxicity oral candidiasis. Platelet dysfunction. purpura nonthrombocytopenic vasculitis

CONTRA-INDICATION

Hypersensitivity to flucloxacillin and other penicillins. Patient with history of flucloxacillin-associated jaundice/hepatic dysfunction.

PREGNANCY:

Not known to be harmful

BREAST FEEDING:

Trace amounts in milk, but appropriate to use.

HEPATIC IMPAIRMENT

Advises caution; including in those with risk factors for hepatic reactions.

RENAL IMPAIRMENT:

With intravenous use Accumulation of electrolytes can occur in patients with renal failure. Dose adjustments

In adults Reduce dose if eGFR less than 10 mL/minute/1.73m².

In children Use normal dose every 8 hours if estimated glomerular filtration rate less than 10 mL/minute/1.73m².

EFFECT ON LABORATORY TESTS

False-positive urinary *glucose* (if tested for reducing substances).

FOOD INTERACTION:

Absorption is reduced by the presence of food.

INTERACTIONS:

May increase the risk of methotrexate toxicity. May decrease the efficacy of oestrogen-containing OC. Enhanced plasma concentrations with probenecid. Bacteriostatic drugs (e.g., chloramphenicol, tetracycline) may interfere with the bactericidal effect of flucloxacillin. May prolong bleeding time in patients on oral anticoagulants.

OVERDOSAGE:

Symptoms: Neurotoxicity (e.g., convulsions, encephalopathy), GI effects (e.g., nausea, vomiting, diarrhoea), blood disorders (e.g., neutropenia, haemolytic anaemia, prolongation of bleeding time, defective platelet function), electrolyte disturbances. Management: Symptomatic treatment.

STORAGE:

Keep tightly closed in cool and dry place. Protect from light. Store below 25°C. Keep away from children.

Manufactured by:
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