



PACKAGE LEAFLET: INFORMATION FOR THE USER

Flucloxacillin 250mg Capsules BP Flucloxacillin 500mg Capsules BP (flucloxacillin sodium)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Flucloxacillin Capsules are and what they are used for
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1. WHAT FLUCLOXACILLIN CAPSULES ARE AND WHAT THEY ARE USED FOR

Flucloxacillin sodium belongs to a class of antibiotics called "penicillinase-resistant penicillins" and is used to treat bacterial infections including:

Skin and soft tissue infections

- Boils, abscesses, carbuncles (A painful localized bacterial infection of the skin and subcutaneous tissue that usually has several openings through which pus is discharged.)
- Furunculosis (A skin condition characterized by the development of recurring boils.)
- Cellulitis (inflammation of tissue below the skin)
- Infected skin conditions e.g. ulcer, eczema, and acne
- Infected wounds, infected burns
- Protection for skin grafts
- Impetigo (a contagious skin disease, esp. of children, usually caused by streptococcal bacteria, marked by a superficial pustular eruption, particularly on the face.)

Respiratory tract infections

- Pneumonia (inflammation of the lungs with congestion.), lung abscess, empyema (a collection of pus in a body cavity, especially in the lung cavity)
- Sinusitis (inflammation of a sinus or the sinuses.)
- Pharyngitis (inflammation of the mucous membrane of the pharynx; sore throat)
- Tonsillitis (inflammation of the tonsils).
- Quinsy (tonsillar abscess.)
- Otitis media (inflammation of middle ear)
- Otitis Externa (Inflammation of the external auditory canal)

Other infections

- Osteomyelitis (affecting the bone and bone marrow)
- Enteritis (affecting the intestinal tract, especially the small intestine)
- Endocarditis (inflammation of the lining of the heart and its valves),
- Kidney, bladder or urethra (the tube which carries urine from the bladder)
- Meningitis (a serious disease characterised by inflammation of the membranes around the brain or spinal cord)
- Septicaemia (blood poisoning).

Flucloxacillin capsules can also be used to prevent infections during major surgery, particularly heart or orthopaedic surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUCLOXACILLIN CAPSULES

Do not take Flucloxacillin Capsules if you:

- Are allergic to penicillins/flucloxacillin sodium or any of the other ingredients in the product (see Section 6)
- Have suffered previously from liver problems (e.g. jaundice) after taking flucloxacillin.
- Have had an allergic reaction to β -lactam antibiotics (e.g. penicillins, cephalosporins).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- are 50 years of age or older
- have other serious illness (apart from the infection this medicine is treating).
- suffer from kidney problems, as you may require a lower dose than normal (convulsions may occur very rarely in patients with kidney problems who take high doses).
- suffer from liver problems, as this medicine could cause them to worsen.
- are taking this medicine for a long time as regular tests of liver and kidney function are advised
- are taking or will be taking paracetamol
- are on a sodium-restricted diet.
- are giving this medicine to a newborn child

There is a risk 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, 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 that must have urgent treatment.

Other medicines and Flucloxacillin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- probenecid or sulfinpyrazone (used in the treatment of gout)
- methotrexate (a chemotherapy drug)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used with general anaesthetics)
- piperacillin (an antibiotic taken by injection)
- warfarin (medicine to prevent blood clotting)
- paracetamol
- Other antibiotics (used to treat infections)

Flucloxacillin Capsules with food and drink

The capsules should be administered half to one hour before meals.

Pregnancy, breast feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tests

Regular monitoring of liver and kidney function should be performed whilst taking flucloxacillin capsules for a long period of time. Tell your doctor that you are taking flucloxacillin capsules if you are having urine tests or blood tests because it may affect the results

Driving and using machines

Flucloxacillin Capsules are not expected to affect your ability to drive or operate machinery.

Flucloxacillin Capsule contains Sodium

This medicine contains less than 1mmol sodium (23mg) per capsule, that is to say essentially 'sodium free'

3. HOW TO TAKE FLUCLOXACILLIN CAPSULES

Always take the capsules exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For **oral use** only.

Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food. It is important that you take your medicine at the right times.

The dose will depend on the patient and will be decided by your doctor. However, the usual doses for each age group are:

- **Adults (including the elderly):** one 250mg capsule four times a day, your doctor may prescribe a different dose for severe infections.
- Joint infections (osteomyelitis) or heart infections (endocarditis) up to 8g daily in divided doses, six to eight hourly.

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- To prevent infection due to surgery- 1 to 2g by injection into a vein, at the same time as the anaesthetic, followed by 500mg six hourly either by mouth or injection into a vein or muscle for up to 72 hours.

Use in children and adolescents

- Children aged 10-18 years – 250mg four times daily
- Children aged 2-10 years: 125mg four times daily.
- Children under 2 years: 62.5mg four times daily.
- Premature or babies less than 4 weeks old: Not recommended.
- Severe kidney disease: your doctor may reduce your dose.

Make sure you complete your prescribed course; do not stop taking Flucloxacillin Capsules if you feel better. If you still feel unwell after finishing the treatment, speak to your doctor.

If you take more Flucloxacillin Capsules than you should
Contact your doctor or nearest hospital casualty department if you or a child have swallowed too much medicine. Take this leaflet and any remaining capsules with you, if possible. Symptoms of overdose include nausea, vomiting, diarrhoea.

If you forget to take Flucloxacillin Capsules

If you miss a dose, take the capsules as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Flucloxacillin capsules

Do not stop treatment early because some bacteria may survive and cause the infection to come back.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flucloxacillin Capsules can cause side effects, although not everybody gets them.

STOP taking Flucloxacillin Capsules and contact your doctor if you experience any of the following:

- Allergic reaction, symptoms of which includes rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue
- Severe bloody diarrhoea (pseudomembranous colitis)
- jaundice (yellow colour in the skin and whites of the eyes), hepatitis (liver inflammation) - sometimes these effects on the liver can 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 that looks like a burn (toxic epidermal necrolysis).
- changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

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

- Minor gastrointestinal disturbances (e.g. diarrhoea, nausea & vomiting)

UNCOMMON: (may affect up to 1 in 100 people)

- Urticaria (itchy skin eruption)
- Purpura (brownish-red spots on the skin)

VERY RARE: (may affect up to 1 in 10,000 people)

- Inflammation of the kidney
- Blood abnormalities i.e. neutropenia and thrombocytopenia, eosinophilia, haemolytic anaemia
- Anaphylactic Shock (severe allergic reaction)
- Angioneurotic Oedema (rapid swelling)
- Pseudomembranous colitis (type of inflammation of the colon)
- Changes in liver function tests
- Erythema multiforme (a red rash caused by hypersensitivity to a drug or disease or other allergen),
- Arthralgia (pain in a joint) and myalgia (pain in the muscles).
- Interstitial nephritis (Nephritis in which the interstitial connective tissue is chiefly affected)
- 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 the treatment.

NOT KNOWN: Frequency cannot be estimated from the available data

- Serious skin reaction - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact your doctor immediately if you get any of these symptoms.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUCLOXACILLIN CAPSULES

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original pack and keep tightly closed.

Do not use the capsules after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flucloxacillin Capsules contains

The **active** substance is flucloxacillin sodium, 250mg or 500mg per capsule.

The **other** ingredients are:

- Magnesium stearate (E572), Colloidal anhydrous silica.
- *Body-* red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), gelatin.
- *Cap -* black iron oxide (E172), titanium dioxide (E171), gelatin.
- *Ink components -* titanium dioxide (E171), shellac (E904), industrial methylated spirits, soya lecithin, dimethyl siloxane, mono- and di-glycerides of fatty acids (E471), methyl cellulose, polyethylene glycol stearate, xanthan gum, benzoic acid, polyethylene glycol, sorbic acid.

See Section 2 'Important information about some of the ingredients of Flucloxacillin Capsules'.

What Flucloxacillin Capsules look like and contents of the pack

The capsules are hard gelatin, elongated with caramel body and black cap printed with 'FLU250MIL' for the 250mg strength, or 'FLU500MIL' for the 500mg strength. They are available in white plastic containers containing 14, 28, 100, 250, 500 and 1000 capsules, or blister strips of 14, 28 and 100 capsules (not all pack sizes may be marketed).

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