

Package leaflet: Information for the user

FLUCLOXACILLIN 250MG CAPSULES
FLUCLOXACILLIN 500MG CAPSULES
 (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 or pharmacist.
- 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 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 are they used for
2. What you need to know before you take Flucloxacillin Capsules
3. How to take Flucloxacillin Capsules
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1. What Flucloxacillin Capsules are and what are they used for

The name of the medicine is Flucloxacillin 250mg or 500mg Capsules which will be referred to as Flucloxacillin Capsules throughout this leaflet. The active ingredient is flucloxacillin.

Flucloxacillin belongs to a group of medicines called Beta-lactamase resistant penicillins. It is an antibiotic used to treat infections by killing the bacteria that cause them.

Flucloxacillin is used to treat the following infections in adults, and children aged 2-10 years. It can also be used in children less than 2 years of age. Your doctor will adjust the dose depending on the age of the patient

- skin and soft tissue infections (including boils, abscesses, carbuncles, ulcers, infected eczema and acne, wounds and burns.
- chest infections (including pneumonia and lung abscess)
- nose and throat infections including tonsils (tonsillitis), sinuses (sinusitis), pharynx (pharyngitis) and ear infections (otitis media and otitis externa).
- heart infections (endocarditis)
- bones and joint infections (osteomyelitis)
- infections of the membranes of the brain (meningitis)
- digestive system infections
- blood infections (septicaemia)
- infections of kidney, bladder and urethra (the tube that carries urine from the bladder)

- Flucloxacillin can also be used to prevent infections during major surgical procedures, particularly in 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 flucloxacillin, any other antibiotics (especially penicillin) or any of the other ingredients of this medicine (listed in section 6)
- have a previous history of jaundice (yellowing of the skin) or liver problems related to flucloxacillin
- you have had an allergic reaction to β -lactam antibiotics (e.g. penicillins, cephalosporins).

Warnings and Precautions:

- If you are taking or will be taking paracetamol

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.

Talk to your doctor or pharmacist before taking Flucloxacillin Capsules if you have or have had any medical conditions, and especially if you:

- have had a skin rash, swelling of the face or neck, or any serious complaint when taking any antibiotic
- are 50 years of age or older
- are suffering from any serious illness (apart from the infection this medicine is treating)
- you 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)
- you suffer from liver problems, as this medicine could cause them to worsen
- are on a low-sodium diet
- are being treated for kidney problems or gout
- are taking this medicine for a long time as regular tests of liver and kidney function is advised.
- The use of flucloxacillin, especially in high doses, may reduce the potassium levels in the blood (hypokalaemia). Your doctor may measure your potassium levels regularly during the therapy with higher doses of flucloxacillin.

New-borns receiving flucloxacillin treatment should be regularly monitored by the doctor.

Other medicines and Flucloxacillin Capsules

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, or might take any other medicines. This is because Flucloxacillin Capsules can affect the way some medicines work. Also some other medicines can affect the way Flucloxacillin Capsules work.

Especially:

- probenecid or sulfinpyrazone (to treat gout)
- methotrexate (a chemotherapy drug)
- oral typhoid vaccine (antibiotics can make it less effective)
- sugammadex (used with general anaesthetics)
- piperacillin (an antibiotic taken by injection)

- warfarin (medicine to prevent blood clotting)
- other antibiotics (used to treat infections)
- paracetamol
- Voriconazole (used against fungal infections)

Pregnant, 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.

Tell your doctor that you are taking Flucloxacillin if you are having urine tests or blood tests because Flucloxacillin may affect the results.

Driving and using machines

Adverse effects on the ability to drive or operate machinery have not been observed.

Flucloxacillin capsules contain Sodium and Benzoates

This medicine also contains methyl hydroxy benzoate and propyl hydroxy benzoate which may cause allergic reactions (possibly delayed).

Information on sodium content:

For 250 mg:

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

For 500 mg:

This medicine contains 26.29 mg sodium per capsule. This is equivalent to 1.31% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Flucloxacillin Capsules

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

- The dosage and duration of treatment will depend on the type and severity of the infection.
- Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food. To reduce the risk of pain in your oesophagus (the tube that connects your mouth with your stomach) swallow capsule with a full glass of water (250 ml) and do not lie down immediately after taking your capsule. Never take more than the recommended dose each day.

The recommended dose is:**Adults:**

- The usual dose is one 250 mg capsule four times a day.
- The dose may be doubled in case of severe infections.
- For infections of the joints (osteomyelitis) or heart (endocarditis), the usual dose is up to 8 g daily in divided doses six to eight hourly.

- To prevent infection due to surgery, 1 to 2g is given intravenously at induction of anaesthesia followed by 500mg every six hours either by mouth or injection into a vein or muscle for upto 72 hours.

Use in children:

- Children aged 10-18 years - 250mg four times daily
- The usual dose for children aged 2-10 years is half the adult dose.
- The dose for children under 2 years old is quarter of the adult dose.
- Premature or babies less than 4 weeks old – Not recommended.

If you still feel unwell after finishing the treatment, speak to your doctor.

Patients with kidney problems

If you suffer from severe kidney failure your doctor will give you lower or fewer doses.

If you take more Flucloxacillin Capsules than you should

It is important to stick to the dose on the label. Taking more than this can make you ill.

If you accidentally take too many capsules, tell your doctor immediately or contact your nearest Hospital Casualty/Accident and Emergency Department even if there are no signs of discomfort. Symptoms of an overdose include feeling or being sick and diarrhoea. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

If you forget to take Flucloxacillin Capsules

If you forget to take a dose, take it as soon as you remember, however, if it is almost time for your next dose then, skip the missed dose and then take your next dose when it is due.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE

If you stop taking Flucloxacillin Capsules

Take all the capsules that have been prescribed for you, even if you start to feel better. Your symptoms may start to improve before the infection is completely treated. If you stop taking the capsules too soon, your symptoms may return.

4. Possible side effects

Like all medicines, this medicine cause side effects, although not everybody gets them.

STOP TAKING this medicine and tell your doctor immediately if you suffer from any of the following:

- hypersensitivity or severe allergic reaction including swollen face or breathing problems.
 - An unexpected skin reaction, e.g. a rash and/or a sore mouth or eyes
- severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
- peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis)
- allergic skin reactions e.g. ‘hives’ or ‘nettle’ rash
- severe diarrhoea with bleeding (pseudomembranous colitis).
- notice your urine becoming darker or your faeces (otherwise known as poo) becoming paler
- hepatitis (inflammation of the liver) sometimes these effects on the liver can be delayed for up to 2 months after finishing treatment

- cholestatic jaundice (skin or white of your eyes turning yellow)
- changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration)
- Inflammation of kidney (interstitial nephritis) is usually reversible when treatment is discontinued, but in rare situations can lead to kidney failure, bowel and/or liver
- joint or muscle pain, this may develop after 2 days or more from the start of treatment with Flucloxacillin
- fever, this may develop after two days or more from the start of treatment with flucloxacillin

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)
- diarrhoea, stomach upset and feeling sick - should be mild and wear off after a few days.

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

- difficulty passing water or blood in urine (may be a sign of inflammation of kidney), anaemia, skin rash with circular, red patches (Erythema multiforme).
- an increase in certain type of white blood cells (eosinophilia).
- 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).

Not Known: (frequency cannot be estimated from the available data)

- serious skin reactions- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). Contact a doctor immediately if you get any of these symptoms.
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm.
- Pain in oesophagus (the tube that connects mouth with stomach) and other related symptoms, such as difficulties in swallowing, heartburn, throat irritation or chest pain.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 package.
- Do not use this medicine after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Flucloxacillin Capsules contain

- The active ingredient is flucloxacillin (as flucloxacillin sodium).
- Flucloxacillin Capsules come in two strengths, 250mg and 500mg. Each capsule contains either 250mg or 500mg of the active ingredient.
- The other ingredients are magnesium stearate.
- The capsule shell contains titanium dioxide (E 171), indigo carmine (E 132), gelatin and sodium lauryl sulphate (SLS). The printing ink composition is shellac, propylene glycol, strong ammonia solution, potassium hydroxide, titanium dioxide (E 171)

What Flucloxacillin Capsules look like and contents of the pack

- The 250 mg capsules are blue coloured printed with “F 250”.
- The 500 mg capsules are blue coloured printed with “F 500”.
- The capsules are supplied in packs containing 28 and 56 capsules.
- Not all the pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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