

FLUCLOXACILLIN 250MG CAPSULES
FLUCLOXACILLIN 500MG CAPSULES

Flucloxacillin



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 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 your medicine is and what it is used for
2. What you need to know before you take your medicine
3. How to take your medicine
4. Possible side effects
5. How to store your medicine
6. Contents of the pack and other information

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

Flucloxacillin is an antibiotic used to treat infections by killing the bacteria that can cause them. It belongs to a group of antibiotics called "penicillins".

Flucloxacillin is used to treat:

- chest infections
- throat or nose infections
- ear infections
- skin and soft tissue infections
- heart infections
- bone and joint infections
- meningitis
- digestive system infections
- blood infections
- kidney, bladder or urethra (the tube which carries urine from the bladder) infections.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE

Do not take this medicine if:

- You are allergic to flucloxacillin or any other penicillin antibiotics (see symptoms in section 4).
- You are allergic to any of the other ingredients of this medicine (listed in section 6).
- You have suffered previously from liver problems (e.g. jaundice) after taking flucloxacillin.
- You 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 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
- You are 50 years of age or older
- You have other serious illnesses (apart from the infection this medicine is treating)
- You are taking this medicine for a long time as regular tests of liver and kidney function are advised
- You are on a sodium-restricted diet
- You have ever had swelling of the face or skin rash while taking an antibiotic
- 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.

Tests

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

Other medicines and Flucloxacillin Capsules

Tell your doctor or pharmacist before taking this medicine if you are taking any other medicines, especially:

- Probenecid or sulfapyrazone (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 taken by injection)
- Warfarin (medicine to prevent blood clotting)
- Other types of antibacterial treatments such as bacteriostatic agents (e.g. chloramphenicol and tetracyclines).

Driving and using machines

Flucloxacillin Capsules have no or negligible influence on the ability to drive and use machines.

Some medicines may affect the way others work. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This means medicines you have bought yourself as well as medicines on

prescription from a doctor.

Pregnancy and breast-feeding

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.

Your medicine contains sodium

This medicinal product contains 52.3mg sodium (main component of cooking/table salt) in each gram. This is equivalent to 2.62 % of the recommended maximum daily dietary intake of sodium for an adult.

To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE YOUR MEDICINE

Always take this medicine exactly as your doctor or pharmacist has told you. Their directions may differ from the information contained in this leaflet. The pharmacist's label should tell you how much to take and how often. Check with your doctor or pharmacist if you are not sure.

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)

- The usual dose is 250mg four times a day.
- Bone or heart infection:
Up to 8g daily, in divided doses at six to eight hours apart.
- Surgical prophylaxis:
1 to 2g IV at induction of anaesthesia followed by 500mg every six hours for up to 72 hours.

Use in children and adolescents

Children (10-18 years of age):
250mg four times daily
Children (2-10 years of age):
125mg four times daily
Children under 2 years of age:
62.5mg four times daily

Patients with kidney problems

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

If you take more of your medicine than you should

If you (or somebody else) accidentally takes too much of your medicine, or you think a child may have taken any, contact your nearest hospital casualty department or speak to your doctor or pharmacist immediately. Symptoms of an overdose include feeling or being sick and diarrhoea.

If you forget to take your medicine

If you forget to take a dose, take it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking your medicine

Keep taking your medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking the medicine, your infection may return or get worse. If you are still unwell after taking all the medicine, go and see your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they occur, they are likely to be temporary, and not serious. However, some may be serious and need medical attention. Prolonged treatment with Flucloxacillin may result in increased growth of resistant organisms.

STOP taking Flucloxacillin Capsules and contact your doctor immediately if you experience:

- allergy or hypersensitivity including itchy rash, itching, sore mouth or eyes, swelling of the face, lips, throat or tongue or breathing problems
- severe, bloody diarrhoea (pseudomembranous colitis). If bloody diarrhoea develops,

flucloxacillin treatment should be discontinued and appropriate therapy, e.g. oral vancomycin should be initiated.

- 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
- skin rash with circular, red patches (Erythema multiforme)
- 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).

These are all very rare side effects (may affect up to 1 in 10,000 people)

Tell your doctor if you notice any of the following effects:

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.
- heartburn and indigestion

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

- rash, itching, red/purple discolourations on the skin.
- hives

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

- kidney problems including inflammation (may result in difficulty passing water or blood in the urine)
- unexplained bleeding or bruising, or skin discolouration (may be caused by changes in the numbers of blood cells)
- joint or muscle pains or fever (may develop 2 days after starting treatment)
- abnormal breakdown of red blood cells (haemolytic anaemia)
- seizures (convulsions)
- changes in liver function test results (reversible when treatment is discontinued).
- blood and lymphatic system disorders like neutropenia (reduction in white blood cells) including agranulocytosis (serious low level of white blood cells). People with this condition are at very high risk of serious infections due to their suppressed immune system. Patients are advised to report any signs and symptoms of infection to their doctor. Thrombocytopenia (low platelet count) and Eosinophilia (an increased number of eosinophils in the blood)
- 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).

Other side effects (frequency not known)

- 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.

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

Check with your doctor if you have any problems while taking this medicine, even if you think the problems are not connected with the medicine, or are not listed in this leaflet.

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 at 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 YOUR MEDICINE

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Securitainers: Store below 25°C. Store in the original package. Keep the container tightly closed in order to protect from light and moisture. Blister packs: Store below 25°C. Do not open the foil pouch until ready to use the product. Once opened the foil pouch may be discarded. Store the product in the outer carton in order to protect from light and moisture.

Return any left-over medicine to the pharmacist. *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 substance is flucloxacillin as flucloxacillin sodium.

The other ingredients are sodium starch glycolate, magnesium stearate, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and gelatin.

Please see further information on sodium in section 2.

What Flucloxacillin Capsules look like and contents of the pack

The 250mg capsules are opaque caramel and grey, printed with 'FXN 250' in black ink. The capsules contain a granular off-white powder. The 500mg capsules are opaque caramel and grey, printed with 'FXN 500' in black ink. The capsules contain a granular off-white powder.

Both strengths are available in the following pack sizes:

Securitainers are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules. Blister packs are available in pack sizes of 15, 18, 20, 21, 28, 30, 50, 100, 250 & 500 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

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