PACKAGE LEAFLET

Package leaflet: Information for the User

Flucloxacillin 250 mg and 500 mg Capsules, hard

(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 the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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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 they are 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 capsules are used to treat:
- chest infections
- throat or nose infections
- ear infections
- skin and soft tissue infections
- heart infections
- bones and joints infections
- meningitis
- digestive system infections
- blood infections
- kidney, bladder or urethra (the tube which carries urine from the bladder) infections.

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 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 Flucloxacillin capsules 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 a known carrier of the HLA-B* 5701 allele.
- you are on a sodium-restricted diet.
- you are giving this medicine to a newborn child.
- 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.

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.

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 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)
- paracetamol
- other antibiotics (used to treat infections)
- voriconazole (used against fungal infections)

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.

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

Flucloxacillin Capsules contain sodium
This medicine contains 46.5 mg sodium (main component of cooking/table salt) per gram. This is equivalent to 2.33% 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.

Take your Flucloxacillin capsules at least 1 hour before or 2 hours after meals.

To reduce the risk of pain in your oesophagus (the tube that connects your mouth with your stomach) swallow capsules with a full glass of water (250 ml) and do not lie down immediately after taking your capsule.

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

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

If you take more Flucloxacillin capsules than you should

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick and diarrhoea.

If you forget to take Flucloxacillin capsules
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and carry on as before, try to wait about four hours before taking the next dose.

If you stop taking Flucloxacillin capsules
Do not stop treatment early because some bacteria may survive and cause the infection to come back.

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. **Stop taking Flucloxacillin capsules and contact your doctor at once** if you experience any of the following:

- 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 (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).
- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)
- 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 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, 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 the treatment.

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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 which is stated on the carton and blister 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 substance is flucloxacillin sodium.

The other excipient is Magnesium Stearate.
The capsule shell contains: Gelatin, titanium dioxide (E171), Indigo carmine (E 132), water.
The printing ink contains: Shellac (E904), dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, titanium dioxide (E171), polysorbate 80.

What Flucloxacillin capsules looks like and contents of the pack

Flucloxacillin 250 mg capsules, hard
Hard gelatine capsule, Size “2” Blue/Blue capsule with printing “fluc/250” on cap and body in white ink containing white to off white granular powder.

Flucloxacillin 500 mg capsules, hard
Hard gelatine capsule, Size “0” Blue/Blue capsule with printing “fluc/500” on cap and body in white ink containing white to off white granular powder.

Both strengths are available in:
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

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