

Package leaflet: Information for the patient

Flucloxacillin 125 mg / 5ml Powder for Oral Solution, Sugar Free
flucloxacillin (as sodium).

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flucloxacillin (as 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What this 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 this medicine

Do not take this medicine:

- if you are allergic to the active substance, other penicillin antibiotics (see symptoms in section 4) or any of the other ingredients of this medicine (listed in section 6).
- Have suffered before from jaundice or liver problems after taking this medicine.
- if 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),
- Suffer from liver problems, as this medicine could cause them to worsen
- Are 50 years of age or older,
- Have other serious illnesses (apart from the infection this medicine is treating).
- Are giving this medicine to a newborn child
- Are on a sodium restricted diet.
- Have ever had swelling of the face or skin rash while taking an antibiotic
- 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking or 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. 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)
- Other antibiotics (used to treat infections),
- Warfarin (medicine to prevent blood clotting).

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.

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.

Driving and using machines

Flucloxacillin oral solution is not expected to affect your ability to drive or operate machinery.

Important information regarding the ingredients of this medicine

This medicinal product contains below ingredients:

Sodium: This medicinal product contains 10.61 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Sodium: This medicinal product contains 21.21 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Aspartame (E951): Contains a source of phenylalanine. May be harmful for people with phenylketonuria.

Mannitol (E421): May have a mild laxative effect.

3. How to take this 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.

How much of your medicine to take and when to take it

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

Adults and children over 10 years (including the elderly): 250 mg four times a day

Children (2-10 years of age): 125 mg four times a day

Children under 2 years of age: 62.5 mg four times a day

Flucloxacillin Sugar Free Oral Solution is not recommended for premature or babies less than 4 weeks old.

Severe kidney disease - your doctor may reduce your dose, the maximum dose in adults is 1 g every 8 to 12 hours.

Instructions for reconstitution of the powder

- a. Remove the cap and add the correct volume of potable water (92 ml if you have been given the 125 mg / 5 ml strength of product and 86 ml if you have been given the 250 mg / 5 ml strength of product).
- b. Replace the cap and shake well.
- c. Remove the cap once more and place the adaptor into the bottle opening. The adaptor should not be removed at any stage.
- d. Replace the cap, do not shake any further.

When to take your medicine

Take your medicine on an empty stomach, at least to one hour before or 2 hours after meals/food. It is important that you take your medicine at the right times.

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.

If you take more of Flucloxacillin Oral solution BP than you should

If you (or somebody else) accidentally take too much Flucloxacillin Oral solution BP, or you think a child may have swallowed 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.

Take your powder for oral suspension 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) take a full glass of water (250ml) after oral suspension intake and do not lie down immediately after oral suspension intake.

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.

STOP taking flucloxacillin and contact your doctor 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. If any hypersensitivity reaction occurs, the treatment should be discontinued.
- Severe, bloody diarrhoea (pseudomembranous colitis)
- Jaundice (yellow colour in the skin and whites of the eyes), hepatitis (liver inflammation) – can be delayed for up to 2 months after finishing treatment
- Severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome) or a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).

- skin rash with circular red patches (erythema multiforme) A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis) (frequency not known). Contact a doctor immediately if you get any of these symptoms.

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, this should be mild and wear off after a few days. If severe or lasting longer, tell your doctor.
 - 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 urine or blood in urine).
 - Unexplained bleeding, bruising or skin discoloration (may be caused by changes in the numbers of blood cells).
 - Abnormal breakdown of red blood cells (haemolytic anaemia)
 - Joint or muscle pains or fever (may develop 2 days after starting treatment).
 - Convulsions (especially with high doses or in patients with severe kidney problems).
 - 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).
 - Changes in liver function test results (reversible when treatment is discontinued).
 - 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** (cannot be estimated from the available data):
 - 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 to flucloxacillin can be delayed for up to 2 months after finishing the treatment.

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 HPRAs website: www.hpra.ie or email to: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

- Keep this medicine out of the sight and reach of children.
- Powder: Do not store above 25°C.
- Reconstituted solution: Store in a refrigerator (2°C – 8°C) and consume within 7 days of preparation.
- 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.
- 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 this medicine contains

- The active substance is flucloxacillin as flucloxacillin sodium.
Each 5 ml reconstituted solution contains flucloxacillin sodium equivalent to 125 mg flucloxacillin.
Each 5 ml reconstituted solution contains flucloxacillin sodium equivalent to 250 mg flucloxacillin
- The other ingredients are aspartame (E951), sucralose, sodium citrate, citric acid anhydrous, disodium edetate, pineapple powder, raspberry flavour, mannitol (E421).

What this medicine looks like and contents of the pack

- Unconstituted powder: a free-flowing white granular powder.
- Reconstituted solution: almost colourless to pale yellow solution with pleasant odour.

- This medicine is available in 150 ml high density polyethylene (HDPE) bottle incorporating an edge pull induction seal wad closed with a child resistant (CRC) cap and a polypropylene measuring cup with 2.5 ml, 5 ml, 10 ml and 15 ml markings.
- On reconstitution, each bottle contains 100 ml of Flucloxacillin Sugar Free Oral Solution.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

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