

PATIENT INFORMATION LEAFLET (RMS)

Package leaflet: Information for the patient

FLUCLOXACILLIN 250MG/5ML ORAL SOLUTION

Flucloxacillin

Read all of this leaflet carefully before you start taking your 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 (chemist).
- 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 250mg/5ml Oral Solution is and what it is used for
2. What you need to know before you take Flucloxacillin 250mg/5ml Oral Solution
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1. WHAT FLUCLOXACILLIN 250MG/5ML ORAL SOLUTION 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
- ear infections
- heart infections
- meningitis
- blood infections
- kidney, bladder or urethra (the tube which carries urine from the bladder) infections.
- throat or nose infections
- skin and soft tissue infections
- bone and joint infections
- digestive system 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 FLUCLOXACILLIN 250MG/5ML ORAL SOLUTION

Do not take Flucloxacillin 250mg/5ml Oral Solution 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
 - 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 giving this to new-borns, other pharmaceutical forms/strengths may be more appropriate for administration to this population
 - You are taking this medicine for a long time as regular tests of liver and kidney function is advised
 - You have ever had swelling of the face or skin rash while taking an antibiotic
 - You have diabetes mellitus or if you have an intolerance to some sugars
 - You are on a sodium restricted diet
 - 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.

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 250mg/5ml Oral Solution

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

- Probenecid or sulfinpyrazone (used to treat gout)
- Methotrexate (used in rheumatoid conditions and cancer)
- Oral typhoid vaccine (antibiotics can make this less effective)
- Sugammadex (used with general anaesthetics)
- Piperacillin (an antibiotic taken by injection)
- Warfarin (medicine used to prevent blood clotting)
- Voriconazole (used against fungal infections)

Please tell your doctor if you are taking other antibiotics (e.g. chloramphenicol, tetracyclines, erythromycins or sulphonamides) when prescribed Flucloxacillin 250mg/5ml Oral Solution as it may affect the action of Flucloxacillin 250mg/5ml Oral Solution.

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.

Driving and using machines

Flucloxacillin 250mg/5ml Oral Solution has no or negligible influence on the ability to drive and use machines.

Tests

Regular monitoring of liver and kidney function should be performed during prolonged treatments.

Tell your doctor that you are taking Flucloxacillin oral solution if you are having liver function tests as Flucloxacillin may affect the results.

If you are having a blood test, you should mention to the doctor or nurse that you are taking flucloxacillin because the antibiotic might affect the blood test result.

Flucloxacillin 250mg/5ml Oral Solution contains sucrose and sodium

This medicine contains 2.96g of sucrose per 5ml dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 24.09mg sodium (main component of cooking/table salt) in each 5ml dose. This is equivalent to 1.20% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 5mg benzoate salt in each dosage unit equivalent of 5ml volume. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

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

3. HOW TO TAKE FLUCLOXACILLIN 250MG/5ML ORAL SOLUTION

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 your medicine on an empty stomach, at least 1 hour before or 2 hours after meals. It is important that you take your medicine at the right times.

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.

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

Adults (including the elderly)

The recommended doses are:

- 250mg four times a day. This may be doubled in serious infections.
- 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

The recommended doses are:

Children over the age of 10: 250mg four times a day

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

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

Patients with kidney problems

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

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

If you take more Flucloxacillin 250mg/5ml Oral Solution than you should

If you (or somebody else) take too much of your medicine, or you think a child may have swallowed any, contact your nearest hospital casualty department or speak to your doctor or pharmacist immediately.

If you forget to take Flucloxacillin 250mg/5ml Oral Solution

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 Flucloxacillin 250mg/5ml Oral Solution

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 250mg/5ml Oral Solution 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. If any hypersensitivity reaction occurs, the treatment should be discontinued
- blood and lymphatic system disorders (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 or sore throat, fever, mouth ulcers, unexplained unusual bleeding or bruising to their doctor
- severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), skin rash with circular, red patches (Erythema multiforme) or a severe rash with reddening, peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis)
- severe, possibly 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 have been delayed for up to 2 months after finishing the treatment
- convulsions (may occur in patients on high doses or with severe kidney problems).

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):

- sore mouth, discolouration of the tongue
- 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 in passing water or blood in the urine)
- unexplained bleeding, bruising or skin discolouration (may be caused by changes in the number of blood cells)
- abnormal breakdown of red blood cells (haemolytic anaemia)
- thrombocytopenia (low platelet count) and Eosinophilia (an increased number of eosinophils in the blood)
- joint or muscle pains or fever (may develop 2 days after starting treatment)
- 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):

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

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.

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 HPRAs Pharmacovigilance, Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUCLOXACILLIN 250MG/5ML ORAL SOLUTION

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

Dry powder: Store below 25°C. Store in the original container in order to protect from light and moisture.

Do not open the foil pouch until ready to reconstitute the product. Once opened the foil pouch may be discarded.

Store the solution at 2°C to 8°C in a refrigerator, and use within 7 days. Store in the original container.

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

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 250mg/5ml Oral Solution contains

- The active substance is flucloxacillin as flucloxacillin sodium. Each 5ml dose contains 250mg of flucloxacillin as flucloxacillin sodium.
- The other ingredients are sodium benzoate (E211), disodium edetate, saccharin sodium, ammonium glycyrrhizinate, sodium citrate anhydrous, pineapple flavour, menthol flavour, erythrosine (E127) and sucrose.
Please see further information on sucrose and sodium in section 2.

What Flucloxacillin 250mg/5ml Oral Solution looks like and contents of the pack

Flucloxacillin 250mg/5ml is a Powder for Oral Solution.

Unconstituted powder: a pink granular powder with a characteristic odour of pineapple.

Reconstituted solution: a pink coloured solution with a characteristic odour of pineapple.

Flucloxacillin 250mg/5ml Oral Solution is available in size 100ml on reconstitution.

Marketing Authorisation Holder:

Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, Ireland.

Manufacturer:

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

PA 1418/016/004

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

Ireland	Flucloxacillin 250mg/5ml Oral Solution
United Kingdom	Flucloxacillin 250mg/5ml Oral Solution BP

This leaflet was last revised in August 2023.