

Package leaflet: Information for the patient

FLUCLOXACILLIN 250MG/5ML ORAL SOLUTION

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
- 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 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.

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 taking this medicine for a long time as regular tests of liver and kidney function are advised

Other medicines and Flucloxacillin 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 (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)

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.

Your medicine contains sucrose and sodium

This medicine contains up to 2.96g of sucrose (sugar) per 5ml dose. This should be taken into account in patients with diabetes mellitus. 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 per 5ml dose. 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 your medicine on an empty stomach, at least thirty minutes to one hour before meals/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) takes too much of your medicine, speak to your doctor or pharmacist immediately.

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 may 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.
- severe, bloody diarrhoea
- 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) or a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).

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. If severe or lasting longer, tell your doctor.

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

- difficulty passing water or blood in the urine (may be a sign of inflammation of the kidney)
- unusual bleeding or bruising, anaemia (may be caused by changes in the numbers of blood cells)
- skin rash with circular red patches (erythema multiforme)

- joint or muscle pains or fever (may develop 2 days after starting 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. 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. The expiry date refers to the last day of that month.

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.

Reconstituted mixture: Store for 7 days at 2°C to 8°C in a refrigerator.

Once reconstituted (mixed) by the pharmacist, this medicine must be used within 7 days.

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 Oral Solution contains

The active substance is flucloxacillin as flucloxacillin sodium.

The other ingredients are sodium benzoate (E211), disodium edetate, saccharin sodium, monoammonium-glycyrrhizinate, sodium citrate, flavour pineapple, flavour menthol, RED FD&C No. 3 (E127) and sucrose.

Please see further information on sucrose in section 2.

What Flucloxacillin Oral Solution looks like and contents of the pack

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 Oral Solution is available in size 100ml on reconstitution.

Marketing Authorisation Holder

Athlone Pharmaceuticals Limited

Ballymurray

Co. Roscommon

Ireland

Manufacturer

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

Distributed by:*

*Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

**Actavis, Barnstaple, EX32 8NS, UK

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PATIENT INFORMATION LEAFLET (CMS)

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- 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.

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1. What your medicine is and what it is used for

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Flucloxacillin is used to treat:

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- 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 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.

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 taking this medicine for a long time as regular tests of liver and kidney function is advised
- You have diabetes mellitus or if you have an intolerance to some sugars
- You are on a sodium restricted diet

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)

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 sucrose and sodium

This medicine contains approximately 2.96g of sucrose (sugar) per 5ml dose. This should be taken into account in patients with diabetes mellitus. 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 per 5ml dose. This should 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 your medicine on an empty stomach, at least thirty minutes to one hour before meals/food. It is important that you take your medicine at the right times.

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)

- 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

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

If you take more of your medicine than you should

If you (or somebody else) take too much of your medicine, speak to your doctor or pharmacist immediately.

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.

STOP taking Flucloxacillin 250mg/5ml Oral Solution 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
- severe skin rash with reddening, flushing, fever, blisters, peeling or ulcers
- severe, possibly bloody diarrhoea
- 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

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

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

- sore mouth, discolouration of the tongue

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

- difficulty in passing water or blood in the urine (may be a sign of kidney problems)
- unusual bleeding or bruising, anaemia – may be caused by changes in the numbers of blood cells
- joint or muscle pains or fever (may develop 2 days after starting treatment)
- convulsions (may occur in patients on high doses or with severe kidney problems)

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

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.

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.

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.
- 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

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 and Manufacturer

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

PA 298/17/4

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 December 2015.