

Package Leaflet: Information for the User

Flucloxacillin 125mg/5ml & 250mg/5ml Powder for Oral Solution, Sugar Free

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. Do not pass it onto others. It may harm them, even if their symptoms 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 is and what it is used for
2. What you need to know before you take Flucloxacillin
3. How to take Flucloxacillin
4. Possible side effects
5. How to store Flucloxacillin
6. Contents of the pack and other information

1. What Flucloxacillin is and what it is used for

Flucloxacillin 125mg/5ml & 250mg/5ml Powder for Oral Solution, Sugar Free contains the active substance flucloxacillin. 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
- bones and joints infection
- meningitis
- digestive system infections
- blood infections
- kidney, bladder or the 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 Flucloxacillin:

Do not take Flucloxacillin and tell your doctor if you or your child:

- are allergic to flucloxacillin, penicillin, any other antibiotic or any other ingredients of this medicine (listed in section 6).

- Have ever had liver problems after taking flucloxacillin.

Warnings and Precautions

Talk to your doctor or pharmacist before taking your medicine if you or your child:

- have liver or kidney problems
- have any serious illness, other than this infection
- are giving this medicine to a newborn child.
- are 50 years old or over
- 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.

Other medicines and Flucloxacillin:

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, Especially:

- Probenecid or sulphinpyrazone (to treat gout)
- other antibiotics (used to treat infections)

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. Tell your doctor that you are taking flucloxacillin if you are having liver function tests as it may affect the results.

Flucloxacillin contains Aspartame, mannitol and sodium

The 125mg/5ml solution contains 5 mg aspartame per 5ml dose, and the 250mg/5ml solution contains 10 mg aspartame per 5ml dose. Aspartame present in this solution, which is a source of phenylalanine. It may be harmful for people with phenylketonuria.

This medicinal product contains mannitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The 125mg/5ml solution contains 15.28mg sodium per 5ml dose, and the 250mg/5ml solution contains 30.56mg sodium per 5ml dose, this is particularly important if you are on a reduced salt diet.

3. How to take Flucloxacillin

Always take Flucloxacillin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the Oral Solution half to one hour before meals. Never take more than the recommended dose each day.

The recommended dose is

- Adults and children over 10 years: 250 mg four times a day.
- 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.
- Children 2 to 10 years: one 125 mg four times a day.
- Children under 2 years: 62.5 mg four times a day, your pharmacist will explain how to give this to your child.
- Premature or babies less than 4 weeks old – Not recommended.
- Severe kidney disease: your doctor may reduce the dose, maximum dose in adults is 1g every 8-12 hours.

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

If you take more Flucloxacillin than you should

If you (or someone else) swallow a lot of Oral Solution at the same time, or you think another 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

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

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 Oral Solution can cause side effects, although not everybody gets them.

Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

Stop taking Flucloxacillin 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).
- 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 resembles burns (toxic epidermal necrolysis).
- A red, scaly rash with bumps under the skin and blisters (Acute generalized exanthematous pustulosis) (frequency not known).

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 or liver, jaundice (skin or the white of your eyes turning yellow), changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration), anaemia, skin rash with circular, red patches (Erythema multiforme), severe skin rash with flushing, fever. Joint or muscle pain or fever, may develop after 2 days or more from the start of treatment with Flucloxacillin

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).

Not Known (frequency cannot be estimated from the available data):

Serious skin reactions - A red, scaly rash with bumps under the skin and blisters (Acute generalized 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.

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 <http://www.medicinesauthority.gov.mt/adrportal>.

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

5. How to store Flucloxacillin Powder for Oral Solution

Do not store above 25°C. Once reconstituted (mixed), store the solution at 2°C to 8°C in a refrigerator and use within 7 days. Do not freeze the medicine. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label/bottle.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Flucloxacillin Powder for Oral Solution contains

The active substance (the ingredient that makes the oral solution work) is flucloxacillin. Each 5ml of solution contains 125mg or 250mg of the active ingredient.

The other ingredients are aspartame, sucralose, sodium citrate, citric acid anhydrous, disodium edetate, pineapple flavour, raspberry flavour, sunset yellow FCF supra, and mannitol.

What Flucloxacillin Powder for Oral Solution looks like and contents of the pack

It is a white granular powder which after reconstitution becomes almost colourless to pale yellow solution having a pleasant odour and a sweet taste.

On reconstitution, each bottle contains 100ml of Flucloxacillin Sugar Free Oral Solution.

Marketing Authorisation Holder:

Ria Generics Limited,
The Black Church
St. Mary's Place, Dublin 7
D07 P4AX, Ireland

Manufacturer:

Wave Pharma Limited
4th Floor Cavendish House
369 Burnt Oak Broadway
Edgware HA8 5AW
Middlesex, United Kingdom

If you would like this leaflet in a different format information or want to report any side effects please contact marketing authorisation holder listed above

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POM