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Package Leaflet: Information for the user

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

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

What is in this leaflet

1. What Flucloxacillin Sugar Free Powder for Oral Solution is and what it is used for
2. What you need to know before you take Flucloxacillin Sugar Free Powder for Oral Solution
3. How to take Flucloxacillin Sugar Free Powder for Oral Solution
4. Possible side effects
5. How to store Flucloxacillin Sugar Free Powder for Oral Solution
6. Contents of the pack and other information

1. WHAT FLUCLOXACILLIN SUGAR FREE POWDER FOR 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 Sugar Free Powder for Oral Solution 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUCLOXACILLIN SUGAR FREE POWDER FOR ORAL SOLUTION

Do not take Flucloxacillin Sugar Free Powder for Oral Solution and **tell** your doctor if you or your child:
- are **allergic** to flucloxacillin, penicillin, any other antibiotic or any of the 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 Flucloxacillin Sugar Free Powder for Oral Solution if you or your child:
- has **liver** or **kidney** problems
- have any **serious illness**, other than this infection
- are **50 years old or over**
- 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 Sugar Free Powder for Oral Solution
Please **tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Especially:
- Probenecid or sulfinpyrazone (to treat gout),
- Methotrexate (a chemotherapy drug),
- Oral typhoid vaccine (antibiotics can make this less effective),
- Warfarin (medicine to prevent blood clotting),
- Piperacillin (an antibiotic taken by injection),
- Sugammadex (used with general anaesthetics),
- Other antibiotics (used to treat infections)
- Voriconazole (used against fungal infections)

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 Oral Solution may have insignificant or no influence on the ability to drive and use machines.

Tests
Regular monitoring of liver and kidney function should be performed whilst taking Flucloxacillin Sugar Free Powder for Oral Solution.
Tell your doctor that you are taking Flucloxacillin Sugar Free Powder for Oral Solution if you are having liver function tests as this medicine may affect the results.

The 250mg/5ml solution contains 20.686 mg sodium per 5ml dose. This medicine contains less than 1 mmol sodium (23mg) per 5ml dose, that is to say essentially "sodium free".

3. HOW TO TAKE FLUCLOXACILLIN SUGAR FREE POWDER FOR ORAL SOLUTION

Always take Flucloxacillin Sugar Free Powder for Oral Solution exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Doses:
- Adults and children over 10 years: 5ml four times a day.
- Children 2 to 10 years: 2.5ml four times a day, your pharmacist will explain how to give this to your child.
- Children under 2 years: 1.25 ml 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.

When to take your medicine
Take powder for oral solution at least 1 hour before or 2 hours after meals. Never take more than the recommended dose each day.
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 solution intake and do not lie down immediately after its intake. It is important that you take your medicine at the right times.

If you take more Flucloxacillin Sugar Free Powder for Oral Solution 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 Sugar Free Powder for Oral Solution
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 Sugar Free Powder for Oral Solution
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, Flucloxacillin Sugar Free Powder for 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 Sugar Free Powder for Oral Solution 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). If bloody diarrhoea develops, flucloxacillin treatment should be discontinued and appropriate therapy should be initiated
- 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.
- blisters or ulcers (Stevens-Johnson syndrome) or a severe rash with reddening, peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis).

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 or feeling sick - 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):
- Hives.

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.
- 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.
- Eosinophilia (an increased number of eosinophils in the blood).
- Joint or muscle pain or fever, may develop after 2 days or more from the start of treatment with Flucloxacillin Sugar Free Powder for Oral Solution.
- 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 (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.
If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, you should contact your doctor or pharmacist.

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 the Yellow Card Scheme at: 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 SUGAR FREE POWDER FOR ORAL SOLUTION

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 in dry place below 30°C,
Store in original package. Protect from light.

Reconstituted solution: Store up to 7 days at 2°C - 8°C in a refrigerator.

Do not throw away any medicines via wastewater. 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 Sugar Free Powder for Oral Solution contains
Each 5ml of sugar free powder for oral solution contains 250mg of flucloxacillin as flucloxacillin sodium.
The other ingredients are mannitol (E421), sucralose, Sodium Citrate, Citric Acid anhydrous, orange flavour and menthol flavour.

What Flucloxacillin Sugar Free Powder for Oral Solution looks like and contents of the pack
Powder: White granular powder, free from agglomerates and caking.
Reconstituted solution: Colourless solution with orange odour.

Flucloxacillin Sugar Free Powder for Oral Solution are available in the size of 100ml on reconstitution in the Translucent HDPE round bottle with White Round polypropylene CR Cap.

Marketing Authorization Holder
Flamingo Pharma (UK) Ltd.
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Manufacturer
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