

## Flucloxacillin 125mg/5ml Sugar Free Powder for Oral Solution

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### 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

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#### 1 What Flucloxacillin Sugar Free 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 Sugar Free Oral Solution

##### Do not take Flucloxacillin Sugar Free Oral Solution if you:

- Are **allergic** to flucloxacillin or any other penicillin antibiotics (see symptoms in section 4)
- Are **allergic** to any of the other ingredients of this medicine (listed in section 6)
- Have had **liver** problems after taking this medicine (flucloxacillin)
- Have had an allergic reaction to  $\beta$ -lactam antibiotics (e.g. penicillins, cephalosporins).

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Flucloxacillin Sugar Free Oral Solution 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
- Are **50 years of age or older**
- Have **other serious illnesses** (apart from the infection this medicine is treating)
- 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 Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you have bought yourself as well as medicines on prescription from a doctor.

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

- Probenecid or sulfapyrazone (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).

#### 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.

#### Flucloxacillin Sugar Free Oral Solution contains sorbitol and sodium.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

**The 125mg/5ml solution contains less than 1mmol sodium (23mg)** per 5ml dose, that is to say essentially 'sodium-free'.

**The 250mg/5ml solution contains 49.41mg sodium** (main component of cooking/table salt) in each 5ml dose. This is equivalent to 2.47% of the recommended maximum daily dietary intake of sodium for an adult. This medicine contains 5mg sodium benzoate in each dose which is equivalent to 5mg/ 5ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

#### 3 How to take Flucloxacillin Sugar Free 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.

#### 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 (including the elderly): 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

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 1g every 8 to 12 hours.

### Instructions for reconstitution of the powder

1. Remove the cap and add the correct volume of potable water (87ml if you have been given the 125mg/5ml strength of product and 79ml if you have been given the 250mg/5ml strength of product)
2. Replace the cap and shake well.
3. Remove the cap once more and place the adaptor (Fig 1) into the bottle opening. The adaptor should not be removed at any stage.
4. Replace the cap, do not shake any further.



Fig 1

### Instructions for use of the syringe

1. Remove the cap and if necessary push the adaptor into the neck of the bottle (Fig 1).
2. Push the plunger of the syringe to remove all the air.
3. Insert the syringe into the adaptor until it is firmly in place (Fig 2).
4. Whilst holding the bottle and syringe shake the contents well.
5. While holding the bottle, turn the entire assembly upside down.
6. Whilst supporting the syringe draw off the required amount of medicine into the syringe (Fig 3).
7. Turn the assembly back up the right way and remove the syringe from the bottle.
8. Replace the cap onto the bottle.



Fig 2



Fig 3

Administer the dose by introducing the tip of the syringe into the mouth of the infant/child, then apply a light pressure on the plunger to slowly release the solution. Keep it out of the reach of children.

Note: For subsequent dosage follow steps 3 and 4 above, before shaking in order to prevent leakage.

### When to take your medicine

Take your powder for oral suspension 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.

### If you take more Flucloxacillin Sugar Free Oral Solution than you should

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

### If you forget to take Flucloxacillin Sugar Free 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 Sugar Free 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.

### STOP taking flucloxacillin and contact your doctor or go to your nearest hospital emergency department immediately if you experience any of the following serious side effects:

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

- 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)
- 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).

**Not known** (frequency 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.

### Other side effects include the following, if they get serious tell your doctor or pharmacist:

- **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. Heartburn and indigestion.
- **Uncommon** (may affect up to 1 in 100 people):  
Rash, itchy, raised skin (hives); purple spots or patches on the skin (purpura).
- **Very rare** (may affect up to 1 in 10,000 people):
  - Inflammation of the kidney or liver, changes in the numbers of blood cells (might cause bleeding, easy bruising or skin discolouration), anaemia, skin rash with circular red patches (erythema multiforme). Joint or muscle pains or fever (may develop 2 days after starting treatment), increase in the number of white blood cells in the blood (eosinophilia).
  - 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):  
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.

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, 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](http://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 Oral Solution

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

Do not store above 25°C.

Once reconstituted (mixed) by the pharmacist, store the solution at 2°C to 8°C in a refrigerator and use within 7 days.

Do not use this medicine after the expiry date which is stated on the label.

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 Sugar Free Oral Solution contains

- The active substance is flucloxacillin as flucloxacillin sodium.
- The other ingredients are sodium citrate anhydrous, disodium edetate, sodium benzoate, citric acid monohydrate, colloidal anhydrous silica, xanthan gum, saccharin sodium, menthol flavour, lemon flavour, strawberry flavour and sorbitol. Please see further information on sorbitol and sodium in section 2.

### What Flucloxacillin Sugar Free Oral Solution looks like and contents of the pack

Unconstituted powder: a free-flowing white granular powder with a slight lemon smell.

Reconstituted solution: an opaque off-white coloured solution with a lemon smell and flavour.

The solution may become more yellow as time progresses.

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

### Marketing Authorisation Holder

Accord Healthcare Limited  
Sage House  
319 Pinner Road  
North Harrow  
Middlesex  
HA1 4HF  
United Kingdom

### Manufacturer

Athlone Laboratories Limited, Ballymurray  
Co. Roscommon, Ireland

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