

## Package leaflet: Information for the patient

### **FLUCLOXACILLIN 125MG/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 Flucloxacillin Oral Solution is and what it is used for
2. What you need to know before you take Flucloxacillin Oral Solution
3. How to take Flucloxacillin Oral Solution
4. Possible side effects
5. How to store Flucloxacillin Oral Solution
6. Contents of the pack and other information

#### **1. WHAT FLUCLOXACILLIN 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 ORAL SOLUTION**

**Do not take Flucloxacillin Oral Solution if you:**

- Are allergic to flucloxacillin or any other penicillin or cephalosporin antibiotics (such as amoxicillin or cefaclor - see symptoms listed in section 4)
- Are allergic to any of the other ingredients of this medicine (listed in section 6)
- Have suffered before from jaundice or liver problems 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
- Suffer from liver problems, as this medicine could cause them to worsen
- Are 50 years of age or older
- Have other serious illnesses (apart from the infection being treated by this medicine)
- Are giving this medicine to a new born child
- Are on a sodium restricted diet.

- Have ever had swelling of the face or skin rash while taking an antibiotic
  - 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.

### 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.

### Other medicines and Flucloxacillin Oral Solution

Tell 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).
- Other types of antibiotics (used to treat infection)
- Voriconazole (used against fungal 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.

### Driving and using machines

Flucloxacillin Oral Solution has no or negligible influence on the ability to drive and use machines.

### Flucloxacillin Oral Solution contains sodium and sucrose.

This medicinal product contains 18mg of **sodium** (main component of cooking/table salt) in each 5ml spoonful of solution. This is equivalent to 0.90% of the recommended maximum daily dietary intake of sodium for an adult.

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

This medicinal product contains 3.094g of **sucrose (sugar)** per 5ml. 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.

### Flucloxacillin Oral Solution contains Sodium Benzoate

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).

### **3. HOW TO TAKE FLUCLOXACILLIN ORAL SOLUTION**

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

#### **When to take Flucloxacillin Oral Solution**

Take Flucloxacillin Oral Solution on an empty stomach, at least 1 hour before or 2 hours after meals. 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.

#### **Doses**

Adults and children over 10 years:	two 5ml spoonfuls four times a day
Children (2-10 years of age):	one 5ml spoonful four times a day
Children under 2 years of age:	half a 5ml spoonful (2.5ml) four times a day

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

#### **If you take more Flucloxacillin Oral Solution than you should**

If you (or somebody else) accidentally take too much of Flucloxacillin Oral Solution, or you think a child may have swallowed any, contact your nearest hospital casualty department or speak to your doctor or pharmacist immediately. Symptoms of an overdose include feeling or being sick and diarrhoea.

#### **If you forget to take Flucloxacillin 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 Oral Solution**

Keep taking Flucloxacillin Oral Solution 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. Please tell your doctor or pharmacist if you notice any of the following side effects or any side effects not listed.

#### **STOP taking Flucloxacillin 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. If any hypersensitivity reaction occurs, the treatment should be discontinued.
- Severe, bloody diarrhoea (pseudomembranous colitis)
- Jaundice (yellow colour in the skin and whites of the eyes), hepatitis (liver inflammation) - can be delayed for up to 2 months after finishing treatment
- Skin rash with circular, red patches (Erythema multiforme).
- Severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)

- Severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).

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 ache and feeling sick. This 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):

- Rash, itching, red/purple discolourations on the skin.

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

- Kidney problems including inflammation (may result in difficulty passing urine or blood in urine)
- Unexplained bleeding, bruising or skin discolouration (may be caused by changes in the numbers of blood cells)
- Abnormal breakdown of red blood cells (haemolytic anaemia)
- Joint or muscle pain or fever (may develop 2 days after starting treatment)
- Convulsions (especially with high doses or in patients with severe kidney problems).
- 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 to their doctor. Thrombocytopenia (low platelet count) and Eosinophilia (an increased number of eosinophils in the blood)
- 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):

- 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 to flucloxacillin can be delayed for up to 2 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

HPRRA Pharmacovigilance,

Website: [www.hpra.ie](http://www.hpra.ie).

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

## **5. HOW TO STORE FLUCLOXACILLIN 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 and the carton. 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.

Store the solution at 2°C to 8°C in a refrigerator. Do not freeze. Store the product in the outer carton.

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

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Flucloxacillin 125mg/5ml Oral Solution contains**

The active substance is flucloxacillin sodium. Each 5ml spoonful contains 125mg of flucloxacillin as flucloxacillin sodium.

The other ingredients are saccharin sodium, sodium benzoate, disodium edetate, ammonium glycyrrhizinate, sodium citrate anhydrous, pineapple flavour, menthol flavour, erythrosine (E127) and sucrose.

Please see further information in section 2.

### **What Flucloxacillin 125mg/5ml Oral Solution looks like and contents of the pack**

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

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

Flucloxacillin 125mg/5ml Oral Solution is available in a size of 100ml upon reconstitution.

### **Marketing Authorisation Holder:**

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

### **Manufacturer:**

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

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