

## Package leaflet: Information for the user

### Floxapen Syrup 125 mg/5 ml Powder for Oral Suspension Floxapen Syrup 250 mg/5 ml Powder for Oral Suspension

Flucloxacillin

**Read all of this leaflet carefully before you start using 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

##### 1 What Floxapen Syrup is and what it is used for

##### 2 What you need to know before you use Floxapen Syrup

##### 3 How to use Floxapen Syrup

##### 4 Possible side effects

##### 5 How to store Floxapen Syrup

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#### 1 What Floxapen Syrup is and what it is used for

Floxapen is an antibiotic used to treat infections by killing the bacteria that can cause them. It belongs to a group of antibiotics called “penicillins”.

Floxapen syrup may be used to treat:

- chest infections.
- throat or nose infections.
- ear infections.
- skin and soft tissue infections.
- meningitis.
- digestive system infections.
- kidney, bladder or the urethra (the tube which carries urine from the bladder) infections.

#### 2 What you need to know before you use Floxapen Syrup

##### Do not use Floxapen syrup:

- if you are **allergic** to flucloxacillin, penicillin, any other antibiotic or any of the other ingredients of this medicine (listed in section 6).
- if you have had an allergic reaction to  $\beta$ -lactam antibiotics (e.g. penicillins, cephalosporins).
- if you have a previous history of flucloxacillin associated jaundice/liver dysfunction.

#### Warnings and Precautions

##### Talk to your doctor, pharmacist or nurse before using Floxapen Syrup if you:

- have **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**.
- have ever had a skin rash or swelling of the face or neck when taking an antibiotic.
- If you 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 Floxapen Syrup

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

- methotrexate, reduced excretion may occur with flucloxacillin (increased risk of toxicity).
- probenecid (to treat gout).

Please tell your doctor if you are taking other antibiotics when prescribed Floxapen as it may affect the action of Floxapen.

### **Floxapen Syrup with food and drink**

Floxapen syrup should be taken half to one hour before meals. (See section 3)

### **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**

There should be no effect on the ability to drive or operate machinery.

### **Tests**

Regular monitoring of liver and kidney function should be performed during prolonged treatments. Tell your doctor that you are taking Floxapen syrup if you are having liver function tests as Floxapen may affect the results.

If you are having a blood test, you should mention to the doctor or nurse that you are taking flucloxacillin because the antibiotic might affect the blood test result.

### **Floxapen Syrup contains Sodium**

Each 5 ml of syrup contains 10.3 mg of sodium. This should be included in the daily allowance of patients on a sodium restricted diet.

### **Floxapen Syrup contains Sucrose**

Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Contains 2.9 g of sucrose per 5 ml dose of Floxapen Syrup 125 mg and contains 2.8 g of sucrose per 5 ml dose of Floxapen Syrup 250 mg. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

### **Floxapen Syrup contains Sodium Benzoate**

This medicine also contains sodium benzoate which is a mild irritant to the skin, eyes and mucous membrane.

## **3 How to use Floxapen Syrup**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. The dose will depend on your age, weight, kidney function as well as the nature and severity of the infection. Check with your doctor or pharmacist if you are not sure. Swallow the syrup **half to one hour before meals**. Never take more than the recommended dose each day.

### **Doses:**

The recommended dose is:

- Adults: total daily dosage of 1 g – 3 g in three to four equally divided doses.

### **Use in children and adolescents**

- Children over 10 years: total daily dosage of 1 g – 3 g in three to four equally divided doses.
- Children under 10 years: 25-50 mg per kg body weight in 24 hours. This will be given in three or four divided doses.
- Your pharmacist will explain how to give this medicine to your child.
- For further dosage instructions, please refer to the label.

If you have severe kidney disease your doctor may reduce the dose.

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

### **If you use more Floxapen Syrup than you should**

If you (or someone else) swallow a lot of syrup 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 Floxapen Syrup**

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 Floxapen Syrup**

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 medicine can cause side effects, although not everybody gets them. Prolonged treatment with Floxapen may result in increased growth of resistant organisms.

**If you notice any of the following serious very rare side effects stop using Floxapen and contact your doctor immediately:**

- Hypersensitivity or severe allergic reaction 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). If bloody diarrhoea develops, flucloxacillin treatment should be discontinued and appropriate therapy, e.g. oral vancomycin should be initiated.
- Skin rash with circular, red patches (Erythema multiforme), 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).

Other side effects include:

**Common (may affect up to 1 in 10 people):**

Minor stomach disturbances e.g. stomach upset or diarrhoea.

**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):**

- 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.
- Changes in numbers of blood cells which may cause unexplained bleeding, bruising or skin discolouration.
- Abnormal breakdown of red blood cells (haemolytic anaemia).
- In patients suffering from kidney failure, neurological disorders with convulsions are possible.
- Inflammation of the liver, jaundice (yellowing of the skin or whites of the eyes). These effects may be delayed for up to two months after treatment has stopped.
- Changes in liver function test results (reversible when treatment is discontinued).
- Joint and/or muscle pain sometimes develop more than 48 hours after the start of the treatment.
- Inflammation of the kidney. This is reversible when treatment is discontinued.
- Fever sometimes develops more than 48 hours after the start of the treatment.

Some of these reactions can be delayed for up to two months after finishing the treatment.

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).

Other side effects (frequency not known)

- Serious skin reactions

A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

Contact a doctor immediately if you get any of these symptoms.

**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 HPRAs Pharmacovigilance, Earlsfort Terrace,

IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).  
By reporting side effects you can help provide more information on the safety of this medicine.

### **5 How to store Floxapen Syrup**

Unopened Dry Powder: Do not store above 25°C.

Following reconstitution: Once reconstituted, Floxapen Syrup remains stable for 14 days stored in a refrigerator at 2-8° C. Do not freeze.

Keep this medicine out of the sight and reach of children. If any medicine is left after two weeks (14 days), return it to your pharmacist.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after the abbreviation EXP.

The expiry date refers to the last day of that month. 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 Floxapen Syrup contains**

- The active substance (the ingredient that makes the syrup work) is flucloxacillin. Each 5 ml contains 125 mg or 250 mg flucloxacillin (as flucloxacillin magnesium).
- The other ingredients are saccharin sodium, sucrose, xanthan gum (E415), citric acid anhydrous, sodium citrate, sodium benzoate (E211), blood orange, tutti frutti and menthol flavours.

#### **What Floxapen Syrup looks like and contents of the pack**

Floxapen syrup comes in a bottle containing 100 ml of a white to off-white liquid mixture, called a suspension. A dosing cup is included.

**To the Pharmacist:** Do not store above 25 C. Add 61ml of water to reconstitute.

**To Dispense:** Check cap seal is intact before using. Unscrew cap to break seal.

Loosen powder, add approximately half the water, invert bottle and shake well. Add the remaining water. Shake to complete the suspension which will take 2-5 minutes.

#### **Marketing Authorisation Holder**

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