

**Package leaflet: Information for the user**

**Floxapen 250 mg & 500 mg Capsules**

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

**What is in this leaflet:**

1. What Floxapen is and what it is used for
2. What you need to know before you use Floxapen
3. How to use Floxapen
4. Possible side effects
5. How to store Floxapen
6. Contents of the pack and other information

**1. What Floxapen 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 capsules are used to treat a wide range of infections caused by bacteria, such as:

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

**2. What you need to know before you use Floxapen**

**Do not use Floxapen**

- if you are **allergic** (hypersensitive) 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 or pharmacist before using Floxapen 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**.
- if you 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**

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:

- 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 with food and drink**

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

### **Pregnancy and breast-feeding**

If you are pregnant, planning to become pregnant or are breastfeeding 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 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 contains sodium**

Each 250 mg capsule contains 13 mg of sodium and each 500 mg capsule contains 25 mg of sodium. To be taken into consideration by patients on a controlled sodium diet.

## **3. How to use Floxapen**

Always take this medicine exactly 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 capsules **whole, with water, half to one hour before meals. Do not chew** the capsules. Never take more than the recommended dose each day.

### **Doses:**

## Floxapen 250 mg & 500 mg Capsules

Adults and 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.  
A liquid formulation is available for children.

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 than you should**

If you (or someone else) take too many capsules at once, or you think a child may have taken 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**

If you forget to take a dose, take it as soon as you remember. Then carry on as before. Try to wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Floxapen**

Do not stop taking the capsules early because some bacteria may survive and cause the infection to come back.

## **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 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):**

- Changes in numbers of blood cells which may cause unexplained bleeding, bruising or skin discolouration.
- 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.
- In patients suffering from kidney failure, neurological disorders with convulsions are possible.
- Abnormal breakdown of red blood cells (hemolytic anaemia).
- 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 HPRA 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**

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

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date stated on the 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 to protect the environment.

**6. Contents of the pack and other information**

Floxapen 250 mg & 500 mg Capsules

**What Floxapen contains**

- The active substance is flucloxacillin. Each capsule contains 250 mg or 500 mg flucloxacillin (as flucloxacillin sodium).
- The other ingredients are magnesium stearate, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) and gelatin.
- The ingredients in the printing ink are shellac, titanium dioxide, povidone and sodium hydroxide.

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

Floxapen 250 mg Capsules are caramel coloured hard gelatin capsules fitted with black caps. They have '250' printed in white on them.

Floxapen 500 mg Capsules are caramel coloured hard gelatin capsules fitted with black caps. They have '500' printed in white on them.

The capsules are available in blister packs of 28 capsules and polypropylene containers of 100 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Actavis Group PTC ehf, Reykjavikurvegi 76-78,  
220 Hafnarfjordur, Iceland

**Manufacturer:**

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**This leaflet was last revised in December 2017**

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