Package leaflet: Information for the user

Floxapen 250 mg Powder for Solution for Injection or Infusion
Floxapen 500 mg Powder for Solution for Injection or Infusion
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

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

Floxapen is used to treat a wide range of infections caused by bacteria including the following:
- chest infections
- throat or nose infections
- ear infections
- skin and soft tissue infections
- heart infections
- bone and joint infections
- meningitis
- infections of the blood
- digestive system infections
- kidney, bladder or urethra (the tube which carries urine from the bladder) infections

Floxapen can also be used to prevent infections following major surgical procedures, particularly in heart or orthopaedic surgery.

2. What you need to know before you use Floxapen

Do not use Floxapen
- if you are allergic to flucloxacillin or any of the other ingredients of this medicine (listed in section 6)

- if you have had an allergic reaction to β-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 ever had a skin rash or swelling of the face or neck when taking an antibiotic
- if you ever had a serious complaint when taking an antibiotic
- if you are being treated for liver problems
- if you are being treated for kidney problems or gout
- if you are on a low sodium diet
- if you are 50 years old or over
- if you have any serious illness, other than this infection
- if you are giving this medicine to a newborn child.
• 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.

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.

If any of the above applies to you, your doctor may prescribe a different medicine or a different dose of Floxapen.

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 (used to treat gout)
- please tell your doctor if you are taking other antibiotics when prescribed Floxapen, as it may affect the action of Floxapen
- voriconazole (used against fungal infections).

Pregnancy and breast-feeding
If you are pregnant, planning to become pregnant or are breast feeding 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 Floxapen because the antibiotic might affect the blood test results.

Floxapen contains sodium
This medicinal product contains approximately 51 mg sodium per g. This should be included in the daily allowance of patients on a sodium restricted diet.

3. How to use Floxapen

Your doctor or nurse will give you this medicine by injection into a muscle (intramuscular) or injection into a vein (intravenous). It can also be given to you by injection into a joint (intra-articular) or injection into the lining of the lung (intrapleural), or by breathing in the medicine from a mask (nebuliser). Floxapen should not be administered into the eye.

Your doctor will decide on the dose and the duration of treatment. This will depend on the severity and type of infection you have.

Dosage may be adjusted in severe kidney failure.

The recommended dose for treating infections is:

Intramuscular or intravenous
Adults and adolescents over 14 years:
1 g – 3 g/day given in three to four divided doses.
For severe infections: up to 8 g daily can be given, administered in 4 infusions (over 20-30 minutes).
No single bolus injection or infusion should exceed 2 g.
Maximum daily dose: 12 g.
To prevent infections after an operation the usual dose is 2 g before the operation when you are given your anaesthetic. This is then followed by 2 g every 6 hours for 24 hours in cases of vascular or orthopaedic surgery and for 48 hours in cases of cardiac or coronary surgery.

Children under 14 years:
25-50 mg per kg body weight in 24 hours. This will be given in three or four divided doses.
Children aged 10-14 years usually receive a daily dose of 1.5 g – 2 g in three to four divided doses.
Children aged 6-10 years usually receive a daily dose of 0.75 g – 1.5 g in three to four divided doses.
For severe infections: Up to 100 mg per kg body weight in 24 hours. This will be given in three or four divided doses each day.
No single bolus injection or infusion should exceed 33 mg per kg body weight.
Dosage adjustment may be necessary in premature babies, newborn babies, breastfed babies and infants.

Floxapen may be administered by other routes, together with systemic therapy:
- By injection into the lining of the lung (intrapleural) and injection into a joint (intra-articular) up to 500 mg once daily.
- Inhalation by nebulizer: 125 mg – 250 mg three times a day.

If you use more Floxapen than you should
As this medicine will normally be given to you by a nurse or a doctor, it is unlikely you will be given too much, but if you think you have been given too much Floxapen tell your doctor or nurse immediately. Signs may be nausea, vomiting and diarrhoea.

If you forget to take Floxapen
As this medicine will normally be given to you by a nurse or a doctor, it is unlikely you will miss a dose, but if you have any concerns discuss this with your doctor or nurse.

If you have any further questions on the use of this product, ask your doctor or healthcare professional.

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 of 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 number 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.
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm.

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, Website: www.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 use this medicine after the expiry date which is stated on the vial and outer carton after the abbreviation EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Once reconstituted, the solutions should be stored in a refrigerator (2-8°C) and used within 24 hours.

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

What Floxapen contains

- The active substance is flucloxacillin. Each vial contains either 250 mg or 500 mg flucloxacillin as flucloxacillin sodium.
- There are no other ingredients.

What Floxapen looks like and contents of the pack

Floxapen powder for solution for injection or infusion is a fine white powder.
Floxapen is supplied in packs of 10 vials in a carton with a package leaflet.

Marketing Authorisation Holder
Teva B.V., Swensweg 5, 2031GA Haarlem, Netherlands

Manufacturer
Istituto Biochimico Italiano Giovanni Lorenzini SPA, Via di Fossignano 2, 04011 –Aprilia (LT), Italy

This leaflet was last revised in June 2023.

The following information is intended for medical or healthcare professionals only:

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Preparation and administration

Please refer to section 3 of the Patient Information Leaflet "How to use Floxapen".
Floxapen may be added to most intravenous fluids (e.g. Water for Injections, Sodium Chloride 0.9%, Glucose 5%, Sodium Chloride 0.18% with Glucose 4%).

Intramuscular: Add 1.5 ml water for injections to 250 mg vial contents or 2 ml Water for Injections to 500 mg vial contents.

Intravenous: Dissolve 250 – 500 mg in 5 – 10 ml Water for Injections. Administer by slow intravenous injection (three to four minutes). Floxapen may also be added to infusion fluids or injected, suitably diluted, into the drip tube over a period of three to four minutes.

Intrapleural: Dissolve 250 mg in 5 – 10 ml Water for Injections.

Intra-articular: Dissolve 250 – 500 mg in up to 5 ml Water for Injections or 0.5% Lignocaine hydrochloride solution.

Nebuliser solution: Dissolve 125 – 250 mg in 3 ml sterile water.

Appearance of the solution: Clear, colourless or pale yellow, particle-free solution.

Stability and Compatibility

Solutions for intramuscular and direct intravenous injection should normally be administered within 30 minutes of preparation. However, aqueous solutions of Floxapen retain their activity for up to 24 hours when stored in a refrigerator (2 – 8°C).

Reconstitution of the injection and preparation of the infusion solutions must be carried out under the appropriate aseptic conditions if these extended storage periods are required.

Stability in Intravenous Infusions

When reconstituted in the following infusion fluids, Floxapen has satisfactory stability for up to 24 hours when stored in a refrigerator (2 – 8°C):

- Water for Injections
- Sodium Chloride Intravenous Infusion (0.9% w/v)
- Glucose Intravenous Infusion (5% w/v)
- Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion

Incompatibilities

Floxapen should not be mixed with blood products or other proteinaceous fluids (e.g. protein hydrolysates) or with intravenous lipid emulsions.

If Floxapen is prescribed concurrently with an aminoglycoside, the two antibiotics should not be mixed in the syringe, intravenous fluid container or giving set as precipitation may occur.