Package leaflet: Information for the user

Floxapen 1000 mg powder for solution for injection/infusion
Floxapen 2000 mg powder for solution for injection/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 belonging to a class of antibiotics called beta-lactamase resistant penicillins. The active substance is flucloxacillin. Flucloxacillin works by killing bacteria that cause infection. It only works with specific strains of bacteria.

Floxapen is used to treat infections such as:

- Skin and soft tissue infections
  - abscesses, cellulites (inflammation of tissue below the skin)

- Respiratory tract infections
  - pneumonia, lung abscess

- Bone and joint infections
  - bone and bone marrow infections (osteomyelitis)
  - arthritis

- Inflammation of the lining of the heart and its valves (endocarditis).

2. What you need to know before you use Floxapen

Do not use Floxapen
- if you are allergic to flucloxacillin or other beta-lactam antibiotics (e.g. penicillins, cephalosporins), or any of the other ingredients of this medicine (listed in section 6)
- if you have previous history of liver problems from taking flucloxacillin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Floxapen
- if you have kidney problems
- if you have liver problems
- 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.

Other medicines and Floxapen
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly:
- Probenecid (used in the treatment of gout)
- Voriconazole (used against fungal infections)

Floxapen may influence the outcome of some blood tests (Guthrie-test).

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 using this medicine.
Floxapen should only be used by pregnant women if considered essential by the doctor. Flucloxacillin passes into breast milk, so ask your doctor for advice before you receive Floxapen.

Driving and using machines
Floxapen is not known to have any affect on your ability to drive or operate machinery.

Floxapen contains sodium
For Floxapen 1 g vial
This medicine contains 51 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.55% of the recommended maximum daily dietary intake of sodium for an adult.

For Floxapen 2 g vial
This medicine contains 102 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 5.1% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Floxapen

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

This medicine will normally be given by an injection of a solution into a vein or a muscle or by intravenous infusion.

For adults and adolescents over 12 years of age the usual dose is:
- 1 g – 6 g a day in 3 to 6 divided doses administered by intravenous or intramuscular injection.

In cases of severe infections up to 8 g per day administered in three to four infusions may be given.

Patients with severe kidney disorders
If you have kidney problems, you may be given a lower dose just twice or three times a day depending on your kidney function.

Children under 12 years of age
25 to 50 mg/kg a day administered in three to four equally divided doses by intravenous or intramuscular injection.
In cases of severe infections up to 100 mg/kg a day in three to four divided doses.
No single bolus injection or infusion should exceed 33 mg/kg.
Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

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 use 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 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 you notice any of the following serious side effects, stop taking Floxapen and contact a doctor immediately:
- Severe prolonged diarrhoea, which may have blood or mucus in it, accompanied with stomach pain and fever. This could be "pseudomembranous colitis".
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be "Stevens-Johnson syndrome" or "toxic epidermal necrolysis".

These effects are very rare, affecting less than 1 in 10,000 people.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)
- Minor gastrointestinal disturbances.

Uncommon side effects (may affect up to 1 in 100 people)
- Skin rash, itchy skin.

Very rare side effects (may affect up to 1 in 10,000 people)
- Abnormal decrease in some types of white blood cells in your blood (neutropenia) which can make you more likely to get infections
- Unusual bleeding or bruising caused by a reduction in the number of platelets in the blood (thrombocytopenia).

- Abnormal increase in a certain type of white blood cells in your blood (eosinophilia). Symptoms include weight loss, night sweats and fever.
- Abnormal breakdown of red blood cells (haemolytic anaemia). Symtoms include tiredness, paleness, yellowing of skin, weakness, dizziness, shortness of breath and fast heart beat.
- Convulsion with very high doses of flucloxacillin in patients with kidney failure.
- Skin rash, which may blister, and looks like small targets central dark spots surrounded by a paler area, with dark ring around the edge (Erythema multiforme).
- Inflammation of the liver (hepatitis), jaundice (cholestatic jaundice).
- Changes to the results of liver function tests.
- Joint pain and muscular pain.
- Swelling of tubes in the kidney.
- Fever.
- 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)
- 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.

Unopened product:
This medicine does not require any special storage conditions.

Reconstituted solution:
When the product is reconstituted with Water for Injection, Sodium Chloride 0.9%, Dextrose 5%, or Sodium Chloride 0.18% with glucose 4%, the chemical and physical in-use stability has been demonstrated for 30 minutes at 20 ºC-25 ºC. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 ºC-8 ºC.

When the product is reconstituted with Hartmann's Solution the reconstituted solution must be used immediately after reconstitution.

Do not use this medicine if there are any visible signs of deterioration.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

For single use only. Discard any unused solution.

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 contains

- The active substance is flucloxacillin. Each vial contains 1 g flucloxacillin (as flucloxacillin sodium). Each vial contains 2 g flucloxacillin (as flucloxacillin sodium)
- The other ingredients: none

What Floxapen looks like and contents of the pack

Floxapen is a white to off-white powder for solution for injection/infusion.

Floxapen 1 g: Type III transparent, clear, glass vials, 20 ml, 20 mm closed with a 20 mm chlorobutylic rubber stoppers and an aluminium sealing ring with a flip-off cap. The vials are placed into carton box.

Floxapen 2 g: Type I transparent, clear, glass vials, 50 ml, 32 mm closed with a 32 mm bromobutylic rubber stoppers and an aluminium sealing ring with a flip-off cap. The vials are placed into carton box.

Packs of 1 vial and 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer

IBI, Istituto Biochimico Italiano 'Giovanni Lorenzini' SPA
Via Fossignano 2, Lazio, 04011 Aprilia (LT)
Italy

This medicine is authorised in the Member States of the European Economic Area under the following names:

Portugal	Floxapen
Austria	Floxapen 2 g Pulver zur Herstellung einer Injektions- bzw. Infusionslösung
Belgium	Flucloxacillin AB 2 g poeder voor oplossing voor injectie of infusie
Ireland	Floxapen 1000mg, Floxapen 2000 mg powder for solution for injection/infusion
Iceland	Floxapen
Netherlands	Flucloxacilline Aurobindo 2 g poeder voor oplossing voor injectie of infusie

This leaflet was last revised in June 2023.

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

For single use only. Discard any unused solution.

Preparation of solution

Floxapen may be added to the following infusion fluids:
Water for Injections, sodium chloride 0.9%, dextrose 5%, sodium chloride 0.18% with glucose 4%, compound sodium lactate intravenous infusion BP (Ringer-Lactate solution; Hartmann's Solution).

Intramuscular:
Add 3.0 ml Water for Injections to 1 g vial contents. Add 4.0 ml water for injections to 2 g vial contents.

Intravenous:
Dissolve 1 g in 20 ml water for injection or 2 g in 40 ml water for injections. Administer by slow intravenous injection. Flucloxacillin may also be added slowly to infusion fluids or injected, suitably diluted, into the drip tube.

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

Reconstituted product:
Reconstitution with Water for injection, Sodium Chloride 0.9 %, Dextrose 5 %, or Sodium Chloride 0.18 % with glucose 4 %:
Chemical and physical in-use stability has been demonstrated for 30 minutes at 20 ºC-25 ºC.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 ºC- 8 ºC.
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.

Reconstitution with Hartmann's solution:
Use immediately after reconstitution.

Incompatibilities
Flucloxacillin should not be mixed with blood products or other proteinaceous fluids (e.g. protein hydrolysates) or with intravenous lipid emulsions.
If flucloxacillin is prescribed concurrently with an aminoglycoside, the two antibiotics should not be mixed in the same syringe, intravenous fluid container or giving set; precipitation may occur.