Fluxapen is an antibiotic belonging to a class of antibiotics called beta-lactamase-resistant penicillins. The active substance is fluxapen. Fluxapen works by killing bacteria that cause infection. It only works with specific strains of bacteria. Fluxapen is used to treat infections such as:

- skin and soft tissue infections
- abscesses, cellulitis (inflammation of tissue below the skin)
- Respiratory tract infections
- pneumonia, lung abscess
- bone and joint infections
- bone and bone marrow infections
- dermatitis (inflammation of the skin)
- arthritise
- Inflammation of the lining of the heart and it valves (endocarditis).

What is in this leaflet:

1. What Floxapen is and what it is used for
2. How to use Floxapen
3. Possible side effects
4. Content of the pack and other information

Technical Approval

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23.01.2017

R.Paul

02.02.2017

R.Paul

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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 medicinal product contains 2.2 mmol (51 mg) sodium per vial. To be taken into consideration by patients on a controlled sodium (salt) diet.

For Floxapen 1 g vial:

This medicinal product contains 4.4 mmol (102 mg) sodium per vial.

For Floxapen 2 g vial:

This medicinal product contains 8.8 mmol (204 mg) sodium per vial.

Severe prolonged diarrhoea, which may have blood in it, accompanied by stomach pain and fever. This could be pseudomembranous colitis.

Sudden wheezing, swelling of your lips, tongue and throat or body, rash, difficulty to breathe.

Tell your doctor or pharmacist if you:

• are allergic to fluclouxacillin or any of the other ingredients of this medicinal product (listed in section 6).

Be sure to read the following information before you receive Floxapen.

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, cellulitis (inflammation of tissue below the skin)
- Respiratory tract infections
- pneumonia, lung abscess
- bone and joint infections
- bone and bone marrow infections
- dermatitis (inflammation of the skin)
- arthritis
- inflammation of the lining of the heart and its valves (endocarditis).

2. 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.

3. Possible side effects

Like all medicines, this medicine can cause side effects in some patients. It is unlikely that everybody gets them.

If you notice any of the following serious adverse side effects, stop taking Floxapen and contact a doctor immediately:

- Sore prolonged diarrhoea, which may have blood in it, accompanied by stomach pain and fever. This could be pseudomembranous colitis.
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, difficulty to breathe. Severe allergic reaction (anaphylaxis).
- Rash, hives, skin rashes, or welts.
- Difficulty to sleep.

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 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.

4. Content of the pack and other information

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

For single use only. Discard any unused solution.

Preparation of solution

Fluxapen may be added to the following infusion fluids:

- intravenous: intravenous infusion (Ringer-Lactate solution; Hartmann’s solution).

- intramuscular: 1 ml of injection for 1 vial content; 1.5 ml of injection for 2 vials content.

Drip tube.

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

In cases of severe infections up to 100 mg/kg/day at three to four divided doses.

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

Intravenous:

Floxapen may be added to the following infusion fluids:

4.0 ml water for injections to 2 g vial contents.

3.0 ml Water for Injections to 1 g vial contents.

(Ringer-Lactate solution; Hartmann’s solution).

Compound sodium lactate intravenous infusion BP 5%, sodium chloride 0.18% with glucose 4%.

Floxapen may be added to the following infusion fluids:

- intravenous: intravenous infusion (Ringer-Lactate solution; Hartmann’s solution).

- intramuscular: 1 ml of injection for 1 vial content; 1.5 ml of injection for 2 vials content.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Intravenous:

Fluxapen may be added to the following infusion fluids:

- intravenous: intravenous infusion (Ringer-Lactate solution; Hartmann’s solution).

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Intravenous:

Fluxapen may be added to the following infusion fluids:

- intravenous: intravenous infusion (Ringer-Lactate solution; Hartmann’s solution).

- intramuscular: 1 ml of injection for 1 vial content; 1.5 ml of injection for 2 vials content.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
These effects are very rare, affecting less than 1 in 10,000 people.

Other side-effects include:

Common side-effects (may affect up to 10 in 100 people):
- Fever (highest temperature distribution)
- Uncommon side-effects (may affect up to 1 in 100 people):
- Headache, itchy skin.

Very rare side-effects (may affect up to 1 in 10,000 people):
- Abnormal decrease in some types of white blood cells, and neutrophilic leukocytosis, which can make you more likely to get infections.
- Unusual bleeding or bruising, due to 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). Symptoms include tiredness, paleness, yellowing of skin, weakness, dizziness, changes of breath and fast heart.
- Convulsions 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 ring around the edge (erythema multiforme).
- Inflammation of the liver (hepatitis), jaundice (icholic jaundice).
- Changes to the results of liver function tests.
- Joint pain and muscular pain.
- Swelling of tubes in the kidney.
- Fever.

Not known (frequency cannot be estimated from the available data):
- Serious skin reactions. A red, scaly rash with bumps under the skin (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 or pharmacist. This is important even if you think the side-effect may possibly be related to another medicine you are taking.

The side-effect information given below refers to reports from the EEA and Switzerland.

For patients:

Reporting of side-effects is important. It can help other patients and healthcare professionals to make decisions about further treatment.

For healthcare professionals:

Reporting of side-effects is an important part of the European Pharmacovigilance System. It can help other patients and healthcare professionals to make decisions about further treatment.

This medicinal product is authorised in the Member States of the EEA under the following names:

- Portugal
  Floxapen

- Austria
  Floxapen 2 g Pulver zur Herstellung eines Injektions-: bzw. Infusionslösungs

- B&K Biochemische Italia ‘Giovanni Lorenzini’
  Floxin 1 g,

- Iceland
  Floxapen

- Austria
  Floxapen 1 g, Floxapen 2 g Pulver zur Herstellung

- Istituto Biochimico Italiano ‘Giovanni Lorenzini’
  Floxin 1 g,

- Italy
  Floxin 1000 mg,

- Spain
  Floxapen 2 g Pulver zur Herstellung

- Netherlands
  Floxapen 2 g poeder voor injectie

This leaflet was last revised in January 2017.

How to store Floxapen

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

Unopened product: This medicinal product 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 stability in-use has been demonstrated for 30 minutes at 20–25 ºC. From a microbiological point of view, the product should be used immediately after reconstitution. If 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 to 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 to protect the environment.

Incompatibilities

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