P0002/01

Package leaflet: Information for the user
Renoxitin 1g Powder for solution for injection or Infusion
Renoxitin 2g Powder for solution for injection or Infusion

Cefoxitin

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Renoxitin is and what it is used for
Renoxitin is a beta-lactam antibiotic in the group of the second-generation cephalosporins.
This medicine is indicated in adults and in adolescents for the treatment of infections when known or suspected to be caused by pathogens susceptible to cefoxitin.
Renoxitin is indicated for:
- complicated urinary tract infections
- pyelonephritis

Cefoxitin may have utility notably in intra-abdominal infections and some gynaecological infections

2. What you need to know before you use Renoxitin
Do not use Renoxitin:
- if you are allergic to cefoxitin, to any other cephalosporin antibiotics or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had a severe allergic (hypersensitive) reaction (e.g., severe skin peeling; swelling of the face, hands, feet, lips, tongue or throat; or difficulty swallowing or breathing) to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Renoxitin.

Allergic reactions
Any signs of an allergic reaction (rash, itching...) during treatment should be immediately reported to your doctor. If a severe, sudden allergic reactions happens, the administration of Renoxitin will have to be stopped. Before you start this treatment, tell your doctor if you have ever developed hives or another type of rash, itching, Quincke's oedema (sudden swelling of the face and neck caused by an allergic reaction) during previous treatment with antibiotics.

Diarrhoea
The occurrence of diarrhoea during antibiotic treatment should not be treated without medical advice. Diarrhoea may develop while you are taking antibiotics, including cefoxitin, or after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, contact your doctor immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
In case of doubt, talk to your doctor or pharmacist.

Neurological disorders
As with all antibiotics belonging to this therapeutic class, the administration of this medicinal product may lead to a risk of encephalopathy (which may result in confusion, disorders of consciousness, seizure, abnormal movements) and, particularly, in case of overdose or kidney dysfunction. If any of these appear, consult your doctor or pharmacist immediately (see sections 3 and 4).

Kidney function
Inform your doctor if you have kidney disease, because your dose may need to be adjusted.
If you are taking other medicines that are harmful for your kidneys or if you use diuretics (water pills), your doctor will monitor your kidney function.

Laboratory tests
Some laboratory test results may be altered while you take this medicine.

Other medicines and Renoxitin
Tell your doctor if you are using, have recently used or might use any other medicines.

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 for advice before taking this medicine.

Pregnancy
Renoxitin should be used during pregnancy only under medical advice.
If you discover that you are pregnant while taking Renoxitin, consult your doctor who is the only person who can judge whether the drug should be continued.

Breast-feeding
Stop breast-feeding while you are using this medicine to avoid any allergic reactions in your baby.

Driving and using machines
Renoxitin has a major influence on the ability to drive and use machines especially because of the possible occurrence of encephalopathy (see sections 3 and 4).

Renoxitin contains sodium.
This medicinal product contains 50 mg of sodium (main component of cooking/table salt) per g. This is equivalent to 2,5% of the recommended maximum daily dietary intake of sodium for an adult. This should be taken into consideration if you are on a controlled-sodium diet.

3. How to use Renoxitin
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor or other Healthcare professional will give you this medicine into one of your veins.

Recommended dose
Your doctor will decide the dose that you need each day and how often the injections/infusions should be administered per day.

The recommended dose may be:
Adults and adolescents: 2g every 4- 6 hours to a maximum of 12g/ day.

Patients with kidney problems
If you have a kidney problem, your doctor may change your dose.

Use in children
There are insufficient data to recommend a posology in children aged up to 11 years.

How to use Renoxitin
Cefoxitin may be administered by slow intravenous injection over a period of 3 to 5 minutes.
A solution of this medicinal product may also be administered by continuous intravenous infusion.
For instructions on reconstitution and dilution of the medicinal product before administration, see information intended for Healthcare professionals.

If you use more Renoxitin than you should
As with all antibiotics belonging to this therapeutic class, the administration of this medicinal product, may lead to a risk of encephalopathy (which may result in confusion, disorders of consciousness, a seizure, abnormal movements) and, particularly, in case of overdose or kidney dysfunction. If any of these appear, consult your doctor or pharmacist immediately (see sections 2 and 4).

If you forget to use Renoxitin
Do not take a double dose to make up for a forgotten dose.
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.

Not known (the frequency is not known):
- Local reactions;
- Local inflammation of the vein with clot formation that may obstruct intravenous administration
- Fever, allergic reactions, Quincke's oedema (sudden swelling of the face and neck caused by allergies), interstitial nephritis (kidney disease).
- Rash that look like that caused by stinging nettles (urticaria), itching and rarely severe skin lesions.
- Nausea, vomiting, diarrhoea; rare cases of pseudomembranous colitis (bowel disease with diarrhoea and abdominal pain) (see Warnings and precautions).
- Blood abnormalities (eosinophilia, leukopenia, neutropenia, agranulocytosis, anaemia, thrombocytopenia, medullary hypoplasia), characterised by elevation of certain blood components (eosinophils) or a decrease in certain blood components which could result in unexplained fever, nosebleeds or bleeding gums, paleness or extreme fatigue. Contact your doctor as soon as possible.
- Increased levels of certain liver enzymes - transient elevation of transaminases (AST, ALT), lactate dehydrogenase, alkaline phosphatase.
- Kidney impairment, especially when certain other medicines are used at the same time (aminoglycosides, diuretics), which could result in abnormal blood test results (elevated creatinine and/or blood urea nitrate).
- Myasthenia gravis exacerbation (muscle disease).
- Serious neurological disorders known as encephalopathy (which may result in confusion, disorders of consciousness, seizure, abnormal movements) and, particularly, in case of high doses or kidney dysfunction (see sections 2 and 3).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Renoxitin
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 label after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

After reconstitution:
Chemical and physical in-use stability has been demonstrated for 8 hours at 25°C and 2-8°C with Water for Injections. From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions are the responsibility of the user.

After dilution of the reconstituted solution with the solvents listed in section 3:
Do not refrigerate.
Chemical and physical in-use stability has been demonstrated for 4 hours at 25 °C.
From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of user.
Do not throw away any medicines via wastewater. 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 Renoxitin contains
- The active substance is cefoxitin sodium.
- Each vial contains 1.0515 g of cefoxitin sodium equivalent to 1000 mg of cefoxitin.
- Each vial contains 2.103 g of cefoxitin sodium equivalent to 2000 mg of cefoxitin.

What Renoxitin looks like and contents of the pack
Renoxitin is a white or almost white powder.
Renoxitin is supplied in vials containing 1 g or 2 g of cefoxitin as the sodium salt, closed with chlorobutyl rubber stopper and sealed with an aluminium capsule with polypropylene flip-off.
Renoxitin 1 g Powder for solution for injection/infusion is available in packs of 1, 5, 10, 20, 25, 50 and 100 vials.
Renoxitin 2 g Powder for solution for injection/infusion is available in packs of 1, 5, 10, 20, 25, 50 and 100 vials.
Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

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ADVICE/MEDICAL EDUCATION

What should you know about antibiotics?
Antibiotics are effective against infections caused by bacteria. They do not work against infections caused by viruses.
Also, your doctor chose to prescribe this antibiotic for you because it suits your particular case and your current illness.
Some bacteria have the ability to survive and reproduce despite the action of an antibiotic. This phenomenon is known as resistance: it inactivates certain antibiotic treatments.
Resistance is the result of abusive or inappropriate use of antibiotics.
You may promote the development of resistant bacteria and therefore delay your recovery or even inactivate this medicine, if you do not:
- take the dose prescribed for you,
- take it as often as prescribed,
- complete the whole course of treatment.

Therefore, to preserve the efficacy of this medication:
1. Do not use an antibiotic unless it has been prescribed by your doctor.
2. Take it exactly as prescribed.
3. Do not reuse an antibiotic without a prescription, even if you think you are treating an illness that appears to be similar.
4. Never give your antibiotic to another person, because it may not be appropriate for that person's illness.
5. Once your treatment is complete, return to your pharmacist any opened boxes so that they can be discarded correctly and appropriately.

The following information is intended for healthcare professionals only:

Special precautions for disposal and other handling
Cefoxitin may be reconstituted with 10 ml water for injections. Immediately after reconstitution, this Cefoxitin solution can be also added to 40 ml of the following solutions, frequently used in infusion(1g or 2g into 50 ml solution, corresponding to 20 to 40mg/ml):
- sodium chloride 0.9%,
- glucose 5% or 10%,
- mixed solution of glucose 5% and sodium chloride 0.9%,
- glucose 5% buffered with sodium bicarbonate 0.02%,
- glucose 5% supplemented with saline solution 0.2% or 0.45%,
- Ringer's Lactate solution,
- mixed solution of glucose 5% and Ringer Lactate,
- mixed solution of fructose 5% or 10% in water for injections,
- fructose 10% solution in saline solution,
- Sodium lactate solution at M/6.

This medicine may be given together with other antibiotics (intravenously with separate syringes or infusions).
When this medicine is administered at the same time as another antibiotic, it is important that the antibiotics are not mixed in the same syringe or infusion.

Reconstitution
Renoxitin should be reconstituted with water for injections: 1 g is soluble in 2 ml. Although, Renoxitin is very soluble, for intravenous use it is preferable to add 10 ml of water for injections to the 1 g vial or to the 2 g vial. It should be shaken to dissolve and then withdraw the entire contents of the vial into a syringe.

Dilution
The reconstituted solution should be diluted with the solvents mentioned above in section 6.6: add around 40 ml of the solvent to the reconstituted solution in order to reach a total volume of 50 ml.
The product should be used immediately after reconstitution/dilution.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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