

Package leaflet: Information for the user

Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion cefotaxime

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.
- 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 Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion is and what it is used for
2. What you need to know before you use Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion
3. How to use Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion
4. Possible side effects
5. How to store Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion
6. Contents of the pack and other information

1. What Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion is and what it is used for

Cefotaxime Reiwa Healthcare contains a medicine called cefotaxime. This belongs to a group of medicines called antibiotics. It works by killing the bacteria that cause infections.

Cefotaxime Reiwa Healthcare is used for infections of the:

- Respiratory tract such as chest and lungs
- The urinary tract
- The skin and soft tissues
- The bones and joints
- Genital tract in women - including infections of the uterus, fallopian tubes and ovaries that can happen pre, post and during pregnancy
- Gonorrhoea - a type of sexually transmitted disease
- The brain (meningitis)

Cefotaxime Reiwa Healthcare may be used to treat bacterial infection of the blood which might be associated with a type of infection mentioned above.

2. What you need to know before you use Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion/

Do not use Cefotaxime Reiwa Healthcare:

- If you are allergic to cefotaxime or any of the other ingredients of this medicine (listed in section 6)
- If you are allergic to certain other antibiotics (e.g. penicillins, cephalosporins)
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefotaxime or other cephalosporins.

Warnings and precautions

Take special care with Cefotaxime Reiwa Healthcare

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with cefotaxime treatment. Stop using cefotaxime and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or pharmacist before using Cefotaxime Reiwa Healthcare if:

- You are allergic to any antibiotics, particularly an antibiotic called penicillin
- You have kidney problems
- You are on a sodium controlled diet
- You have ever had severe diarrhoea after taking some antibiotics ('Pseudomembranous colitis').
If you experience severe diarrhoea, you should contact your doctor straight away as you may need urgent medical attention

Other medicines and Cefotaxime Reiwa Healthcare

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Concomitant intake of

- Other antibiotics (such as penicillins, aminoglycosides, tetracyclines, erythromycin and chloramphenicol)
- diuretics (e. g. furosemide)
- probenecid (for the treatment of gout and arthritis) may increase or decrease the effect of cefotaxime.

Inform your doctor if you are in treatment with these medicines.

As with other cephalosporins a positive Coombs' test, which means a false positive reaction for glucose in urine, may occur.

Cefotaxime Reiwa Healthcare with food and drink

Cefotaxime Reiwa Healthcare can be used with or without food.

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.

Cefotaxime excretes in breast milk in low concentrations. Therefore it should not be used during breast-feeding.

Driving and using machines

You may start to move abnormally, suffer from sudden involuntary muscle contractions, dizziness or feel less alert. If this happens, do not drive or use any tools or machines

Important information about some of the ingredients of Cefotaxime

This medicinal product contains 2.09 mmol (or 48 mg) of sodium per 1 g of cefotaxime. To be taken into consideration by patients on a controlled sodium diet.

3. How to use Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion/

How Cefotaxime Reiwa Healthcare is given:

- Your medicine will normally be given to you by a doctor or nurse.
- It will be given by injection into a vein or muscle
- It can also be given as an infusion through a drip into a vein

How much Cefotaxime Reiwa Healthcare is given:

- Your doctor will decide on how much Cefotaxime Reiwa Healthcare to give you
- The dose will depend on the type of infection and any other illnesses you may have
- You may be given a different dose depending on your weight
- The dosage and frequency of your treatment will depend on your infection
- If you have any kidney problems you may be given a lower dose of Cefotaxime Reiwa Healthcare.

The usual dose is:

Adults and adolescents (12 to 16-18 years)

Mild to Moderate infection:

- 1g every 12 hours

Severe infection:

- Up to 12g each day

Children

Mild to Moderate infection:

- 50-150 mg for every kilogram of body weight
- This is given once a day in 2 to 4 divided doses

Severe infection:

- Up to 200mg for every kilogram of body weight once a day

Neonates

The recommended dosage is 50mg/kg/day in 2 to 4 divided doses. In severe infections 150-200mg/kg/day, in divided doses, have been given.

The following table may serve as a guide to dosages

Age	Daily dose of cefotaxime
0-7 days	50mg/kg/day every 12 hours IV
8 days-1 month	50mg/kg/day every 8 hours IV

If you use more Cefotaxime Reiwa Healthcare than you should

This is not likely, as the injection is given to you by a doctor.

If you feel bad after administration of the injection, please contact your doctor immediately.

If you forget to use Cefotaxime Reiwa Healthcare

Not relevant, as the injection is given to you by a doctor.

If you stop using Cefotaxime Reiwa Healthcare

The doctor will continue treatment with cefotaxime until the infection treated is relieved. If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Cefotaxime Reiwa Healthcare can cause side effects, although not everybody gets them. These side effects are usually mild and last for a short time.

Stop taking cefotaxime and tell your doctor immediately if you notice any of the following symptoms:

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug

hypersensitivity syndrome).

- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment if:

- You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- You have blistering of the skin, mouth, eyes or genitals. This may be something called , Stevens-Johnson syndrome“ or , Toxic Epidermal Necrolysis“ or Acute generalised exanthematous pustulosis (AGEP)
- You have sudden involuntary muscle contractions or begin to lose consciousness. This is called “encephalopathy”
- You feel your heart flutter
- Severe watery diarrhoea, possibly with blood and mucus ('Pseudomembranous colitis')
- you notice changes in the way your kidneys are working

Tell your doctor or nurse if any of the following side effects get serious or lasts longer than a few days:

- You bruise more easily and get more infections than usual. This could be because of a blood disorder.
- Reactions at the site of the injection including reddening of the skin, pain or swelling
- Feeling or being sick (vomiting), diarrhoea
- Feeling tired or unwell
- Dizziness or headache
- Liver problems such as jaundice or hepatitis that may cause your eyes or skin to go yellow and your urine to become darker
- Fits
- Irregular heartbeat (palpitations)
- Difficulty breathing, wheezing, tightness in the chest (something called“bronchospasm”)
- Skin rash
- Blood in your urine. This could be due to a kidney problem (called interstitial nephritis)
- Fever
- Infection

Other side effects include:

- Blood and kidney problems or changes in the way your kidney works. These would show up in the results of blood tests.
- A Jarisch-Herxheimer reaction that may cause skin rash, itching, fever, blood and liver problems, difficulty in breathing and joint discomfort.

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <, > <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefotaxime Reiwa Healthcare 1g powder for solution for injection/infusion/

- Keep out of the sight and reach of children.
- Do not use Cefotaxime Reiwa Healthcare after the expiry date which is stated on the label and carton <after EXP>. The expiry date refers to the last day of the month.
- Vials of Cefotaxime Reiwa Healthcare powder must not be stored above 25 °C. Store in the original carton in order to protect from light.
- For the reconstituted solution: chemical and physical in-use stability has been demonstrated for 12 hours at 2-8°C. 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 12 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

- Do not use this medicine if you notice that the solution contains particles or is cloudy.
- Do not throw away any medicines via wastewater. 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 Cefotaxime Reiwa Healthcare contains

- The active substance is Cefotaxime (as Cefotaxime Sodium). Each vial contains 1 g of cefotaxime.
- There are no other ingredients.

What Cefotaxime Reiwa Healthcare looks like and contents of the pack

- Cefotaxime Reiwa Healthcare powder is white to pale yellow-white crystalline powder.
- Cefotaxime Reiwa Healthcare powder will be mixed with the water for injections to make a straw-coloured solution which is ready for use as an injection or an infusion (a drip).
- Available in packs of 1 and 10 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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