

CEFTRIAZONE POWDER FOR SOLUTION FOR INJECTION 500 MG, 1000 MG CEFTRATAJ

Package leaflet:

Information for the patient

Ceftriaxone Powder for Solution for Injection.

Read all of this leaflet carefully before you start taking 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).

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1.WHAT CEFTRIAZONE FOR INJECTION ARE AND WHAT THEY ARE USED FOR

Ceftriaxone is an antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Ceftriaxone is used to treat infections of

- the brain (meningitis).
- the lungs.
- the middle ear.
- the abdomen and abdominal wall (peritonitis).
- the urinary tract and kidneys.
- bones and joints.
- the skin or soft tissues.
- the blood.
- the heart.

It can be given:

- to treat specific sexually transmitted infections (gonorrhoea and syphilis).
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection.
- to treat infections of the chest in adults with chronic bronchitis.
- to treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age.
- to prevent infections during surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFTRIAZONE FOR INJECTION

You must not been given Ceftriaxone for injection:

- if you are allergic to ceftriaxone or any of the other ingredients of this medicine (listed in section 6).
- if you have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling

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of the hands, feet and ankles, and a severe rash that develops quickly.

- if you are allergic to lidocaine and you are to be given Ceftriaxone for injection as an injection into a muscle.

Ceftriaxone for injection must not be given to babies if:

- The baby is premature.
- The baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is to be given a product that contains calcium into their vein.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before you are given Ceftriaxone for injection if:

- You have recently received or are about to receive products that contain calcium.
- You have recently had diarrhoea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- You have liver or kidney problems.
- You have gall stones or kidney stones.
- You have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness).
- You are on a low sodium diet.

If you need a blood or urine test

If you are given Ceftriaxone for injection for a long time, you may need to have regular blood tests. Ceftriaxone for injection can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

- Tell the person taking the sample that you have been given Ceftriaxone for injection. If you are diabetic or need to have your blood glucose level monitored you should not use certain blood glucose monitoring systems which may estimate

blood glucose incorrectly while you are receiving ceftriaxone. If you use such systems check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary.

Children

Talk to your doctor or pharmacist or nurse before your child is administered Ceftriaxone for injection if:

- He/She has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and Ceftriaxone for injection

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- A type of antibiotic called an aminoglycoside.
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes).

Pregnancy, breast-feeding and fertility

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 taking this medicine. The doctor will consider the benefit of treating you with Ceftriaxone against the risk to your baby.

Driving and using machines

Ceftriaxone for injection may cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

Ceftriaxone for injection contains sodium

Ceftriaxone for injection contains 3.6mmol (or 82mg) for the 1g vial and 7.2mmol (or 165mg) for the 2g bottle of sodium per dose. To be taken

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into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE CEFTRIAXONE FOR INJECTION

Ceftriaxone for injection is usually given by a doctor or nurse. It can be given as:

- a drip (intravenous infusion) or as an injection directly into a vein or
- into a muscle.

Ceftriaxone for injection is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

The recommended dose

Your doctor will decide the correct dose of Ceftriaxone for injection for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given Ceftriaxone for injection depends on what sort of infection you have.

Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):

- 1 to 2g once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose (up to 4g once a day). If your daily dose is higher than 2g, you may receive it as a single dose once a day or as two separate doses.

Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:

- 50-80 mg ceftriaxone for each kg of the child's body weight once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a

higher dose up to 100 mg for each kg of body weight to a maximum of 4g once a day. If your daily dose is higher than 2g, you may receive it as a single dose once a day or as two separate doses.

- Children with a body weight of 50 kg or more should be given the usual adult dose.

Newborn babies (0-14 days)

- 20 – 50 mg Ceftriaxone for each kg of the child's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

People with liver and kidney problems

You may be given a different dose to the usual dose. Your doctor will decide how much Ceftriaxone for injection you will need and will check you closely depending on the severity of the liver and kidney disease.

If you are given more Ceftriaxone for injection than you should

If you accidentally receive more than your prescribed dose, contact your doctor or nearest hospital straight away.

If you forget to use Ceftriaxone for injection

If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a missed dose.

If you stop using Ceftriaxone for injection

Do not stop taking Ceftriaxone for injection unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

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Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Severe allergic reactions (not known, frequency cannot be estimated from the available data)

If you have a severe allergic reaction, tell a doctor straight away.

The signs may include:

- Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and ankles.

Severe skin rashes (not known, frequency cannot be estimated from the available data)

If you get a severe skin rash, tell a doctor straight away.

- The signs may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
- Loose stools or diarrhoea.
- Changes in the results of blood tests for liver functions.
- Rash.

Uncommon (may affect up to 1 in 100 people)

- Fungal infections (for example, thrush).
- A decrease in the number of white blood cells (granulocytopenia).
- Reduction in number of red blood cells (anaemia).
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
- Headache.
- Dizziness.
- Feeling sick or being sick.
- Pruritis (itching).
- Pain or a burning feeling along the vein where Ceftriaxone for injection has been given. Pain where the injection was given.
- A high temperature (fever).

- Abnormal kidney function test (blood creatinine increased).

Rare (may affect up to 1 in 1,000 people)

- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Difficulty in breathing (bronchospasm).
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- Blood or sugar in your urine.
- Oedema (fluid build-up).
- Shivering.

Not known (Frequency cannot be estimated from the available data)

- A secondary infection that may not respond to the antibiotic previously prescribed
- Form of anaemia where red blood cells are destroyed (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.
- Inflammation of the mucus lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder, which may cause pain, feeling sick and being sick.
- A neurological condition that may occur in neonates with severe jaundice (kernicterus).
- Kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.
- A false positive result in a Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (an abnormal build up of the sugar galactose).
- Ceftriaxone for injection may interfere with some types of blood glucose tests - please check with your doctor.

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

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report side effects directly via the national reporting systems listed below.

United Kingdom Yellow Card Scheme
www.mhra.gov.uk/yellowcard or search for
MHRA Yellow Card in the Google Play or
Apple App Store Ireland HPRA
Pharmacovigilance Earlsfort Terrace IRL -
Dublin 2 Tel: +353 1 6764971 Fax: +353 1
6762517 Website: www.hpra.ie E-mail:
medsafety@hpra.ie

By reporting side effects you can help provide
more information on the safety of this medicine.

5. HOW TO STORE CEFTRIAZONE FOR INJECTION

**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. The expiry date
refers to the last day of that month
- The vials and bottles should not be stored
above 25°C
- Keep the vial or bottle in the outer carton in
order to protect from light
- From a microbiological point of view, the
product should be 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°C to 8°C, unless
reconstitution has taken place in controlled and
validated aseptic conditions. Once reconstituted,
any unused portion of solution should be
discarded.

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 FURTHER INFORMATION

What Ceftriaxone for Injection contain

- The active substance is ceftriaxone sodium.
Each container contains the equivalent of 1g or
2g of ceftriaxone. The sodium content is
approximately 82mg (3.6mmol) for the 1g vial
and 165mg (7.2mmol) for the 2g bottle.

What Ceftriaxone for Injection look like and contents of the pack

Ceftriaxone for injection is a white to pale
yellow powder, which must be made into a
solution before injection or infusion. Ceftriaxone
for injection 1g is available in packs of 1, 5, 10,
25 or 50 vials. Not all pack sizes are marketed.
Ceftriaxone for injection 2g is available in packs
of 1 or 10 bottles. Not all pack sizes are
marketed.

Manufactured by:

Taj Pharmaceuticals Limited

Kerala, Bavla, Dist. Ahmedabad - 438225
Gujarat, INDIA

Marketing Authorization

Holder:

Regal sun co., Ltd. Myanmar