

SCHEDULING STATUS:**S4**

CEFTRIAZONE 1000 INJECTION RESMED

Dry, sterile Ceftriaxone Sodium U.S.P. equivalent to Ceftriaxone 1 g (intramuscular or intravenous.)

Sugar free.

Sodium content approximately 83 mg (3,6mEq) per vial.

Read all of this leaflet carefully before you start taking Ceftriaxone 1000 Injection Resmed.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What Ceftriaxone 1000 Injection Resmed is and what it is used for
2. What you need to know before you take Ceftriaxone 1000 Injection Resmed
3. How to take Ceftriaxone 1000 Injection Resmed
4. Possible side effects
5. How to store Ceftriaxone 1000 Injection Resmed
6. Contents of the pack and other information

1. What CEFTRIAZONE 1000 INJECTION RESMED is and what it is used for

CEFTRIAZONE 1000 INJECTION RESMED is an antibiotic used for treating infections including chest infections (such as pneumonia), ear, nose and throat infections, gonorrhoea, infection of the membrane covering the brain (meningitis), infections of the blood stream, as well as bone, joint, soft tissue, skin, kidney and bladder infections. It is also used to prevent and treat infections after surgical operations.

2. What you need to know before you take Ceftriaxone 1000 Injection Resmed

You or your newborn baby should not be administered CEFTRIAZONE 1000 INJECTION RESMED:

- if you are allergic to cephalosporin or penicillin antibiotics.

- if your newborn baby has jaundice, especially if your baby is a premature newborn baby with jaundice.
- if your newborn baby is also given calcium-containing products.

Warnings and precautions

Take special care with Ceftriaxone 1000 Injection Resmed

- it may cause interference with certain laboratory tests.
- You must not be given calcium-containing solutions or products within 48 hours of your last dose of **CEFTRIAXONE 1000 INJECTION RESMED**. Talk to your doctor or pharmacist or nurse before your child is administered Ceftriaxone 1000 Injection Resmed if he or she has recently been given or is to be given a product that contains calcium into their vein.
- Antibiotic treatment can affect the normal bacteria in the gut, causing a new infection (colitis). Tell your doctor immediately if you develop diarrhoea after starting treatment with **CEFTRIAXONE 1000 INJECTION RESMED**.

Tell your doctor if you are having blood and urine tests. CEFTRIAXONE 1000 INJECTION RESMED may interfere with these tests.

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.

Talk to your doctor or pharmacist or nurse before you are given Ceftriaxone 1000 Injection Resmed if:

- You have recently had diarrhoea after having an antibiotic medicine or if you have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- You experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of

white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4 “Possible side effects”).

- 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.

Other medicines and Ceftriaxone 1000 Injection Resmed

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. This medicine is excreted into breast milk and your healthcare provider will consider the benefit of treating you with Ceftriaxone 1000 Injection Resmed against the risk to your baby.

3. How to use Ceftriaxone 1000 Injection Resmed

Do not share medicines prescribed for you with any other person.

Always use CEFTRIAXONE 1000 INJECTION RESMED exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of CEFTRIAXONE 1000 INJECTION RESMED is too strong or too weak, tell your doctor or pharmacist. CEFTRIAXONE 1000 INJECTION RESMED will be administered to you as an injection. You will not be expected to give yourself CEFTRIAXONE 1000 INJECTION RESMED. It will be given to you by a person who is qualified to do so. The usual dose for adults (including the elderly) is 1 g once daily until at

least 48 to 72 hours after the infection appears to have cleared. The dose for babies and children up to 12 years old will depend on bodyweight. Your doctor will decide the best dose for you. Your doctor or nurse will prepare your injection by dissolving the ceftriaxone powder in a suitable fluid for injection. The solution will be injected intramuscularly (into a muscle) or intravenously (into a vein) by slow injection or by slow infusion (drip). CEFTRIAXONE 1000 INJECTION RESMED may be administered with a 1% lignocaine solution to reduce pain at the site of an intramuscular injection. The lignocaine solution must never be given intravenously.

If you are given more CEFTRIAXONE 1000 INJECTION RESMED than you should

Since a health care provider will administer Ceftriaxone 1000 Injection Resmed, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Missed CEFTRIAXONE 1000 INJECTION RESMED dose

Since a health care provider will administer Ceftriaxone 1000 Injection Resmed, it is unlikely that the dose will be missed.

Stopping Ceftriaxone 1000 Injection Resmed treatment

Your doctor will tell you how long your treatment with CEFTRIAXONE 1000 INJECTION RESMED will last.

4. Possible side effects

CEFTRIAXONE 1000 INJECTION RESMED can have side effects.

Not all side effects reported for Ceftriaxone 1000 Injection Resmed are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Ceftriaxone 1000 Injection Resmed, please consult your health care provider for advice.

Very serious side effects:

If any of the following happens, stop using Ceftriaxone 1000 Injection Resmed and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 reactions, signs of which may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting ceftriaxone treatment for infections with spirochete such as Lyme disease.

Frequent side effects:

- 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.

Less frequent side effects:

- 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 the injection was given.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).
- 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.
- 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 buildup of the sugar galactose).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store Ceftriaxone 1000 Injection Resmed

Store at or below 30^o C. Keep product in outer container until required for use. Protect from light. KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What Ceftriaxone 1000 Injection Resmed contains

The active ingredient is ceftriaxone 1000 mg.

What Ceftriaxone 1000 Injection Resmed looks like and contents of the pack

Ceftriaxone 1000 Injection Resmed is a white to yellowish orange crystalline powder contained in 10 ml clear glass vials sealed with rubber stopper and blue flip off aluminum seal. Each 10ml vial is packed into a printed monocarton.

Holder of Certificate of Registration

Resmed Healthcare

71 Rochdale Road, Springfield Park, Durban, 4051.

Registration number

53/20.1.1/0171