Scheduling Status: S4

CEPHTRIFECT 500 (powder for solution for injection)

CEPHTRIFECT 1 000 (powder for solution for injection)

CEPHTRIFECT 2 000 (powder for solution for injection)

Ceftriaxone

Sugar free

Read all of this leaflet carefully before you are given CEPHTRIFECT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, your pharmacist, nurse, or other health care provider.
- CEPHTRIFECT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CEPHTRIFECT is and what it is used for
2. What you need to know before you are given CEPHTRIFECT
3. How CEPHTRIFECT is given
4. Possible side effects
5. How to store CEPHTRIFECT
6. Contents of the pack and other information

1. What CEPHTRIFECT is and what it is used for

CEPHTRIFECT is an antibiotic used to treat infections in different parts of the body, caused by bacteria.

Ceftriaxone is also used to prevent infections following surgery.

Ceftriaxone will not work against infections caused by viruses such as colds or the flu.

Ceftriaxone belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

2. What you need to know before you are given CEPHTRIFECT

CEPHTRIFECT should not be administered to you:

- If you are hypersensitive to ceftriaxone, other cephalosporins or any of the ingredients of CEPHTRIFECT (listed in section 6).
- If you have had a serious allergic reaction to any penicillins or similar antibiotics (such as cephalosporins, carbapenems or monobactams). Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, sudden swelling of the hands, feet and ankles, chest pain, severe skin rash, itching or hives.

CEPHTRIFECT 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

Tell your doctor or health care provider before being given the injection:

- If you have had any type of allergic reaction to any cephalosporin or penicillin medicines (symptoms may include: rash, red skin, blistering of the lips, eyes and mouth, skin peeling, high fever, flu-like symptoms).
- If you have recently received or are about to receive products that contain calcium.
- If you have liver or kidney problems.
- If you have gallstones or kidney stones.
- If 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).
- If you have a disease of the brain (symptoms include: decreased level of consciousness, altered mental state, sudden involuntary (unintended) jerking of a muscle or group of muscles and fits).
- If you are allergic to lignocaine or other local anaesthetics. Lignocaine can be mixed with CEPHTRIFECT prior to injection.
- *If you have allergies to:*
    - any other medicines.
    - any other substances, such as foods, preservatives or dyes.
- *If you have, or have had any medical conditions, including:*
    - kidney disease.

- stomach or bowel problems.
- liver disease.
- bleeding problems.

Diarrhoea:

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after CEPHTRIFECT has been stopped. Do not take any diarrhoea medicine without first checking with your doctor. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Fungal infections:

If you get a sore white mouth or tongue while being given or soon after stopping CEPHTRIFECT, tell your doctor or pharmacist. Also, tell your doctor or pharmacist if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of ceftriaxone allows fungi to grow and the above symptoms to occur. CEPHTRIFECT does not work against fungi.

Laboratory tests:

If you have to test your urine for sugar while you are being given CEPHTRIFECT, make sure your doctor knows which type of test you use. CEPHTRIFECT may affect the results of some of these tests.

If you have to have any blood tests, tell your doctor you are being given this medicine. CEPHTRIFECT may affect the results of some blood tests.

Other medicines and CEPHTRIFECT

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

If you are about to start taking any new medicine, remind your doctor and pharmacist that you are being given CEPHTRIFECT.

Tell any other doctors, dentists or pharmacists who treat you that you are using CEPHTRIFECT.

Tell your doctor or health care provider if you are taking any of the following medicines:

- Aminoglycosides (antibiotic used to treat bacterial infections).
- Calcium containing products.
- Anticoagulants (medicines used to treat blood clots).
- Diuretics (also called water pills, are medications used to help the kidneys get rid of salt and water by increasing the amount of urine produced).

- Chloramphenicol (used to treat infections, particularly of the eyes).
- Hormonal contraceptives (used for the prevention of pregnancy).

Pregnancy and breastfeeding

Safety in pregnancy has not been established. CEPHTRIFECT passes into breast milk and should be used with caution if you are breastfeeding your baby.

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 being administered CEPHTRIFECT.

Driving and using machines

CEPHTRIFECT may cause dizziness in some people.

It is not always possible to predict to what extent CEPHTRIFECT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CEPHTRIFECT affects them. If you feel dizzy after receiving CEPHTRIFECT, do not drive or use machines until you feel better.

3. How to receive CEPHTRIFECT

CEPHTRIFECT must only be given by a doctor or nurse. You will not be expected to give yourself CEPHTRIFECT. It will be given to you by a person who is qualified to do so.

CEPHTRIFECT can be given in two ways:

- As a slow injection into a vein.
- As a deep injection into a large muscle.

Your doctor will decide what dose and how long you will receive CEPHTRIFECT. This depends on your condition and whether you are taking any other medicines. For most infections, CEPHTRIFECT is usually given once a day. If you have the impression that the effect of CEPHTRIFECT is too strong or too weak, talk to your doctor or pharmacist.

The length of treatment is usually between 4 days and 2 weeks.

Sometimes only a single dose of CEPHTRIFECT is required for the treatment and prevention of certain infections.

If you have received more CEPHTRIFECT than you should:

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

If you forget to use CEPHTRIFECT:

Since a health care provider will administer CEPHTRIFECT, it is unlikely that the dose will be missed.

4. Possible side effects

CEPHTRIFECT can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- 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).

These are all very serious side effects. If you have them, you may have had a serious reaction to CEPHTRIFECT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).
- 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 CEPHTRIFECT treatment for infections with spirochetes such as Lyme disease.
- Fits (seizures).
- Difficulty breathing.
- Less urine than is normal for you or kidney stones.
- A neurological condition that may occur in new-borns with severe jaundice (kernicterus).
- Hepatotoxicity (fever, nausea, vomiting, yellowing of your eyes and skin).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Irregularities 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.
- Increased liver functions seen in blood test results.
- Rash.

Less frequent side effects:

- Secondary infection due to taking antibiotics, fungal infections (for example, thrush).
- Watery and severe diarrhoea, which may also be bloody.
- A decrease in the number of white blood cells (granulocytopenia).
- Anaemia (symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale).
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
- Headache.
- Dizziness.
- Brain dysfunction with symptoms such as confusion, memory loss, personality changes and/or coma in the most severe form.
- Sudden involuntary (unintended) jerking of a muscle or group of muscles.
- Nausea or vomiting.
- Itching or swelling of the skin.
- Swelling or clotting in the veins.
- Blood or glucose (sugar) in your urine.
- Pain at injection site.
- Inflammation of the veins (symptoms such as redness, warmth and pain in the affected area).
- High temperature, chills.
- Fever, shivering, irregular kidney function test.

Unknown frequency side effects:

- Form of anaemia, illness resulting from the destruction of red blood cells (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Spinning sensation (vertigo).
- Inflammation of the pancreas, mouth or tongue.
- Problems with your gallbladder (gallstones), which may cause pain or feeling sick.
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).
- 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).
- CEPHTRIFECT may interfere with some types of blood glucose tests - please check with your doctor

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CEPHTRIFECT.

5. How to store CEPHTRIFECT

Store all medicines out of reach of children.

Store at or below 25 °C in the outer carton to protect the medicine from light.

The reconstituted solution is intended for immediate use, but the solution may be stored in the original vials in the refrigerator at 2 °C to 8 °C for 48 hours or below 25 °C for 24 hours.

Do not use CEPHTRIFECT if you notice:

- The packaging is torn or shows signs of tampering.
- The expiry date on the pack has passed.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CEPHTRIFECT contains

CEPHTRIFECT 500: Each vial contains dry, sterile ceftriaxone sodium equivalent to 0,5 g ceftriaxone.

CEPHTRIFECT 1 000: Each vial contains dry, sterile ceftriaxone sodium equivalent to 1,0 g ceftriaxone.

CEPHTRIFECT 2 000: Each vial contains dry, sterile ceftriaxone sodium equivalent to 2,0 g ceftriaxone.

What CEPHTRIFECT looks like and contents of the pack

CEPHTRIFECT 500 powder for solution for injection:

White to yellowish powder in a 15 ml injection vial made of colourless glass, with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

CEPHTRIFECT 1 000 powder for solution for injection:

White to yellowish powder in a 15 ml injection vial made of colourless glass, with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

CEPHTRIFECT 2 000 powder for solution for injection:

White to yellowish powder in a 30 ml injection vial made of colourless glass, with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

On reconstitution, a yellowish to brown-yellow clear solution is obtained.

Packs for IM, IV injection or for IV infusion containing:

CEPHTRIFECT 500, 1 000, 2 000 powder for solution for injection is packed in cartons containing 1 or 10 single dose colourless glass vial/s with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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Access to the corresponding Professional Information

The Full Professional Information Leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.