

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

TRIAXIPHIN 250 mg; TRIAXIPHIN 500 mg; TRIAXIPHIN 1 g Injection

Ceftriaxone

Sugar free

Read all of this leaflet carefully before you start receiving TRIAXIPHIN

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

What is in this leaflet

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

1. What TRIAXIPHIN is and what it is used for

TRIAXIPHIN contains the active ingredient ceftriaxone sodium, which is an antibacterial agent used for treatment of infections caused by bacteria.

TRIAXIPHIN is an antibiotic used for the treatment of bacterial infections. It is also used prior to some surgical operations to reduce the risk of bacterial infections.

2. What you need to know before you take TRIAXIPHIN

TRIAXIPHIN should not be administered to you if:

- If you are allergic to TRIAXIPHIN or other medicines containing related antibiotics such as cephalosporins or penicillins.
- If TRIAXIPHIN is mixed together with calcium-containing solutions or products, or if TRIAXIPHIN is going to be administered to you through an intravenous infusion line which contains calcium- containing fluid, it could cause a precipitation of ceftriaxone-calcium salt.
- If you have had a bad reaction to a lidocaine/lignocaine injection in the past.

TRIAXIPHIN **must not be given to babies if:**

- If the baby is premature.
- If the baby is newborn (up to 28 days) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is about to be given another injection that contains calcium.

Warnings and precautions

Before starting treatment, make sure your doctor knows:

- if you have both a liver and a kidney condition.
- if you have recently received or are about to receive calcium.
- if you have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- if you have other illnesses, such as blood problems in children (such as jaundice).
- if you have allergies, particularly to cephalosporins, penicillins, or similar antibiotics.
- if you are on a low sodium diet.
- if 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").

Children and adolescents:

- Newly born babies, infants and children will receive a dose based on their age and bodyweight.

Other medicines and TRIAXIPHIN

- Before starting treatment, make sure your doctor knows if you are taking other medicines (including complimentary and traditional medicines and those not prescribed by your doctor). This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. For example, if you are taking oral contraceptives you will need to use another additional method of contraception while you are being treated with TRIAXIPHIN and for one month after finishing your treatment.
- TRIAXIPHIN should not be added to solutions containing calcium.
- Unwanted effects have been observed with the combination of medicines containing chloramphenicol and ceftriaxone.
- If you are taking medicine to reduce the clotting of your blood, tell your doctor before you receive TRIAXIPHIN.

If you need a blood or urine test

If you are given TRIAXIPHIN for a long time, you may need to have regular blood tests. TRIAXIPHIN 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 TRIAXIPHIN.
- 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 TRIAXIPHIN. 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.

TRIAXIPHIN with food and drink

The use of TRIAXIPHIN with food and drink has not been established.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor or pharmacist or other healthcare professional for advice before taking TRIAXIPHIN.

Safety and efficacy has not been established. You should not receive TRIAXIPHIN when you are pregnant or breastfeeding your baby.

Driving and using machines

TRIAXIPHIN can cause drowsiness. If you feel dizzy, do not drive or use any tools or machines.

Talk to your doctor if you experience these symptoms

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per the maximum recommended dose, that is to say essentially 'sodium-free'

3. How to take TRIAXIPHIN

Depending on the nature of your illness, your bodyweight, your age and your individual response to TRIAXIPHIN, your doctor will administer the correct dose into your muscle (*IM*) or vein (*IV*).

If you receive more TRIAXIPHIN than you should

Your doctor will prescribe the appropriate care for you should you receive more than the required amount of TRIAXIPHIN.

If you did not receive your TRIAXIPHIN therapy

Your doctor will prescribe the appropriate care you should receive.

Effects when treatment with TRIAXIPHIN is stopped:

The duration of TRIAXIPHIN therapy varies, depending on the nature of your illness and your individual response to the treatment.

You will receive TRIAXIPHIN for at least 2 - 3 days after starting to recover from your illness or after a surgical operation to prevent infections from occurring.

4. Possible side effects

Not all side effects reported for TRIAXIPHIN are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking TRIAXIPHIN, consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. TRIAXIPHIN may cause side effects, even when used as directed.

The following side effects may occur in patients during treatment: **Severe allergic reactions**

If you have a severe allergic reaction, tell your doctor as soon as possible.

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 reactions

If you get a severe skin reaction, tell your doctor as soon as possible.

The signs 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).

Other possible side effects:

Frequent

- 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

- Fungal infections affecting the genital regions
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever
- 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
- Pain or a burning feeling along the vein where TRIAXIPHIN has been given.
- Pain where the injection was given.
- Abnormal kidney function test (blood creatinine increased).
- Fever
- shivering,
- wheezing

- temporary liver problems
- other types of infection, e.g. yeasts.
- 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.

Frequency Unknown

- 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.
- Inflammation of the liver

- Injury that combines hepatocellular injury, lobular disarray, varying degrees of inflammation and canicular cholestasis and is associated with drug-induced liver injury
- 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).
- TRIAXIPHIN may interfere with some types of blood glucose tests - please check with your doctor.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TRIAXIPHIN.

5. How to store TRIAXIPHIN

Store at or below 25 °C.

Protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Storage Directions for Reconstituted Product:

Store for up to 6 hours at or below 25 °C or 24 hours at 2 – 8 °C.

Do not freeze the reconstituted product.

Store all medicines out of the reach and sight of children.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What TRIAXIPHIN contains

The vials contain 250 mg, 500 mg, and 1 g of ceftriaxone as the sodium salt. Each gram of TRIAXIPHIN contains approximately 3, 6 mmol sodium. There are no other ingredients.

What TRIAXIPHIN looks like and contents of the pack

Sterile, white to yellowish-orange powder in clear glass vials.

Contents of the pack:

TRIAXIPHIN 250 mg: 10 ml Clear glass vial with grey bromo butyl stopper and aluminium flip off seal with green plastic top, containing powder equivalent to 250 mg ceftriaxone for reconstitution.

Vials are supplied in cartons containing singles.

TRIAXIPHIN 500 mg: 10 ml Clear glass vial with grey bromo butyl stopper and aluminium flip off seal with light blue plastic top, containing powder equivalent to 500 mg ceftriaxone for reconstitution. Vials are supplied in cartons containing singles.

TRIAXIPHIN 1 g: 15 ml Clear glass vial with grey bromo butyl stopper and aluminium flip off seal with grey plastic top, containing powder equivalent to 1 g ceftriaxone for reconstitution.

Vials are supplied in cartons containing singles.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD.

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STORMILL

EXT.1

ROODEPOORT

1724

SOUTH AFRICA

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