

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Rocephin® 250 mg; Rocephin[□] 500 mg; Rocephin[□] 1 g and

Rocephin® 2 g injection

Ceftriaxone sodium

Sugar free

Water for injection (injection)

Read all of this leaflet carefully before you start receiving Rocephin

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

What is in this leaflet

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

1. What Rocephin is and what it is used for

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

Rocephin 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 receive Rocephin

You should not receive Rocephin:

- If you are allergic to Rocephin or other medicines containing related antibiotics such as cephalosporins or penicillins.
- If Rocephin is mixed together with calcium-containing solutions or products, or if Rocephin 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.

Rocephin must not be given to babies if:

- The baby is premature.
- 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.
- have recently received or are about to receive calcium.
- Have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- have other illnesses, such as blood problems in children (such as jaundice).
- have allergies, particularly to cephalosporins, penicillins, or similar antibiotics.
- are on a low sodium diet.
- 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 Rocephin

- 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 Rocephin and for one month after finishing your treatment.
- Rocephin 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 Rocephin.

If you need a blood or urine test

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

Pregnancy and breastfeeding

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

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

Driving and using machines

Rocephin 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.

3. How Rocephin is given

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

If you receive Rocephin than you should

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

If you did not receive your Rocephin therapy:

Your doctor will prescribe the appropriate care you should receive.

Effects when treatment with Rocephin is stopped:

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

You will receive Rocephin 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 Rocephin are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking Rocephin, 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. Rocephin 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 (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 Rocephin has been given.
- Pain where the injection was given.
- Abnormal kidney function test (blood creatinine increased).
- Fever
- shivering,
- wheezing
- temporary liver problems
- fungal infections affecting the genital regions

- 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.

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).
- Rocephin 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. This includes any possible side effects not listed in this leaflet. 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 Rocephin.

5. How to store Rocephin

Store at or below 30 °C. Keep product in outer container until required for use.

Storage Directions for Reconstituted Product:

Store for up to 6 hours at or below 25 °C or 24 hours in the refrigerator at 2 - 8 °C.

This medicine should not be used after the expiry date (EXP) shown on the pack.

Store out of reach of children.

6. Contents of the pack and other information

What Rocephin contains:

The vials contain 250 mg, 500 mg, 1 g or 2 g of ceftriaxone as the sodium salt. Each gram of Rocephin contains approximately 3,6 mmol sodium. There are no other ingredients.

What Rocephin looks like and contents of the pack

Packs for *IM* or *IV* injection containing sterile, whitish powder in clear glass vials;

Rocephin 250 mg: 1 vial with dry substance equivalent to 250 mg ceftriaxone and 1 ampoule water for injection 5 mL.

Rocephin 500 mg: 1 vial with dry substance equivalent to 500 mg ceftriaxone and 1 ampoule water for injection 5 mL. Packs of 50 vials with no water for injection.

Rocephin 1 g: 1 vial with dry substance equivalent to 1 g ceftriaxone + 1 ampoule water for injection 10 mL. Packs of 143 vials with no water for injection.

Packs for IV infusion containing

Rocephin 2 g: 1 vial with dry substance equivalent to 2 g ceftriaxone. Packs of 50 vials with no water for injection.

Not all packs may be marketed.

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

24 Fricker Road

Illovo

Gauteng

South Africa

Roche Ethical Assistance Line toll-free: 0800 21 21 25

8. Registration numbers

Rocephin 250 mg R/20.1.1/0044

Rocephin 500 mg R/20.1.1/0045

Rocephin 1 g R/20.1.1/0046

Rocephin 2 g R/20.1.1/0047

Water for Injection H/34/0128

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