PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ROCIJECT 0,5 g (powder for injection)

ROCIJECT 1 g (powder for injection)

ROCIJECT 2 g (powder for injection)

Ceftriaxone sodium

Sugar free

Read all of this leaflet carefully before you are given ROCIJECT

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

1. What ROCIJECT is and what it is used for

The active ingredient of ROCIJECT, ceftriaxone, belongs to a group of medicines known as the cephalosporins. It is used in the treatment of infections caused by bacteria. It works by killing bacteria or preventing their growth.

It is used in the treatment of various infections.

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

You should not be administered ROCIJECT

- if you are hypersensitive (allergic) to ceftriaxone (the only ingredient in ROCIJECT);
- if you are allergic to other cephalosporin antibiotics or penicillin;
- if you are allergic to lidocaine (lignocaine) and you are going to be injected with ROCIJECT into a muscle.
- ROCIJECT must not be given to premature babies or newborn babies (up to 28 days) who have certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or who will have to be injected with a medicine that contains calcium.

Warnings and precautions

Tell your doctor or healthcare provider before being given ROCIJECT injection:

- if you are allergic to any medicine or other substance not mentioned in the previous section;
- if you are about to receive calcium containing medicines;
- if you have gut problems (inflammation of the bowel), as ROCIJECT may worsen the condition (see section 4);

- if you have been diagnosed with blood disorders, such as bleeding problems or if you have anaemia (reduction in red blood cells which can make the skin look pale and cause weakness or breathlessness). ROCIJECT may worsen these conditions (see section 4);
- if you have any kidney or liver problems;
- if you are on a low sodium diet.

If any of the above apply to you, or if you are not sure, talk to your doctor or professional healthcare provider before you receive ROCIJECT.

Other medicines and ROCIJECT

Always tell your healthcare provider if you are taking any other medicine.

This includes complementary or traditional medicines.

This is especially important with the following medicines as they may interact with ROCIJECT Injection:

- Calcium-containing injections or solutions for dilution, as they may form insoluble particles when in contact with ROCIJECT
- Chloramphenicol (an antibiotic used for various infections).
- Oral contraceptive tablets (the pill). ROCIJECT can stop the pill from working. To prevent unplanned pregnancy, you should also make use of additional contraceptive methods (such as condoms) during treatment with ROCIJECT and up to one month thereafter.

These medicines may be affected by ROCIJECT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are given ROCIJECT.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

ROCIJECT may not be used during pregnancy or if you breastfeed your baby.

Driving and using machines

ROCIJECT may make you feel dizzy. Do not drive as ROCIJECT could interfere with your ability to drive safely. Do not operate any tools or machines.

ROCIJECT contains sodium

ROCIJECT contains sodium (as ceftriaxone sodium). Tell your doctor if you are on a sodium restricted diet.

3. How to receive ROCIJECT

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

You will not be expected to give ROCIJECT to yourself. It will be given to you by a doctor or healthcare professional.

ROCIJECT is given by intramuscular injection, intravenous injection or by intravenous infusion.

Your doctor will tell you how long your treatment with ROCIJECT will last; it will depend on the type of infection you have and how serious it is.

Dosing

The exact amount of medicine is carefully worked out by your doctor.

If you receive more ROCIJECT than you should

A healthcare professional will administer ROCIJECT and control the dosage according to your doctor's instructions.

Please tell your doctor or healthcare professional if you have any concerns.

In the unlikely event of receiving an overdose your doctor will manage the overdosage.

If you missed a dose of ROCIJECT

You need not remember when to get your next dose; you will be cared for in hospital by a healthcare professional, who will ensure that you receive the correct amount of ROCIJECT at the right time.

If you stop taking ROCIJECT

It is important that the course of treatment your doctor has prescribed is finished. Do not stop having ROCIJECT just because you feel better.

Do not stop receiving treatment before your doctor wants you to stop; the germs causing the infection may become resistant to ceftriaxone, the active ingredient in ROCIJECT.

4. Possible side effects

ROCIJECT can have side effects.

Not all side effects reported for ROCIJECT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving ROCIJECT, please consult your doctor, pharmacist or other healthcare provider for advice.

Tell your doctor straight away if you notice any of the following very serious side effects – you may need urgent medical treatment:

- Severe allergic reactions, including a shock reaction. You may have sudden swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, allergic facial swelling, severe dizziness with very fast heartbeat and heavy sweating.
- If you have a serious allergic skin reaction, with signs like a severe rash, hives (nettle rash), skin peeling, itching, fever and possibly blisters in the mouth.

These side effects occur less frequently.
If you have these serious side-effects, you need urgent medical attention.

Tell your doctor or healthcare professional immediately if you have the following side effects:

- Severe inflammation of the large bowel. Some signs may be stomach pain, diarrhoea with mucous and mostly with blood and fever.
- Convulsions (“fits”).
- Infections caused by yeasts or moulds (for example thrush in the mouth or vagina).
- Kidney problems such as having blood in your urine, problems passing water (urine), or passing less water than usual or if you do not pass water at all.
- Inflammation of the pancreas (pancreatitis). Signs may be a severe pain in the stomach, which spreads to your back.

- Inflammation of the liver and gallbladder. Some signs may be nausea, vomiting, loss of appetite abdominal pain, dark urine, light coloured stools, tiredness, yellowing of the skin or whites of the eyes.

These side effects occur either less frequently or at unknown frequency.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Loose stools, nausea (feeling sick), vomiting (being sick).

Side effects occurring less frequently:

- Too few red blood cells or their haemoglobin content is too low (anaemia). Some signs may be that you feel unusually tired or weak.
- Blood clotting problems. Some signs may be that you have nosebleeds, bleed easily, bruise easily and have pain and swelling of your joints.
- A lowered white blood cell count (such as leukopenia). Tell your doctor if you have a sudden high temperature (fever), are shivering and have a sore throat and get more infections than usual.
- Headache, feeling dizzy.
- A sore mouth and tongue. Tell your doctor if your tongue is swollen, red and sore.
- Pain, redness or burning at the place where ROCIJECT was injected.
- Fever (a high temperature) and shivering.

Some side effects such as certain blood, kidney or liver problems can only be seen during routine tests that your doctor may order. Examples are:

- Liver problems (these problems are shown in blood tests).

- Sugar in the urine (as seen in urine tests).
- Positive results in a Coombs' test (a test for some blood problems).
- Damage to the liver.

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 or nurse. 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 ROCIJECT.

You are also asked to report any suspected adverse reactions to Acino Pharma (Pty) Ltd.

E-Mail: drugsafety_ZA@arceralifesciences.com.

5. How to store ROCIJECT

Store at or below 25 ºC and protect from light.

Keep vials in carton until required for use.

Reconstituted product: Store for up to 6 hours below 25 ºC or up to 24 hours in a refrigerator (2-8 ºC).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Your healthcare professional will check that the ROCIJECT is not past its expiry date stated on the label and carton before giving you the injection.

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

6. Contents of the pack and other information

What ROCIJECT contains

- **The active substance** is ceftriaxone (as ceftriaxone sodium).

  ROCIJECT is available in single dose vials each containing dry sterile ceftriaxone sodium as the active ingredient, equivalent to 0,5 g ceftriaxone, 1 g ceftriaxone, or 2 g ceftriaxone (I.M., I.V., or for I.V. infusion).

- **Inactive** ingredients:

  ROCIJECT does not contain any inactive ingredients.

What ROCIJECT looks like and contents of the pack

What ROCIJECT looks like

Sterile, almost white or yellowish, crystalline powder in clear glass vials.

Reconstituted solution: Clear, pale yellow to amber solution.

Contents of the pack

Packs for I.M., I.V. or for I.V. infusion containing:

Single dose clear, colourless, Type 1 borosilicate, 10 ml glass vial with dry substance equivalent to 0,5 g ceftriaxone in packs with 1 or 10 vials.

Single dose clear, colourless, Type 1 borosilicate, 10 ml glass vial with dry substance equivalent to 1 g ceftriaxone in packs with 1 or 10 vials.

Single dose clear, colourless, Type 1 borosilicate, 10 ml glass vial with dry substance equivalent to 2 g ceftriaxone in packs with 1 or 10 vials.

Holder of certificate of registration

Acino Pharma (Pty) Ltd

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This leaflet was last revised in

16 July 2026

Registration numbers

ROCIJECT 0,5 g: 37/20.1.1/0368

ROCIJECT 1 g: 35/20.1.1/0345

ROCIJECT 2 g: 37/20.1.1/0352

Access to the corresponding professional information

The corresponding professional information can be found in the packaging of ROCIJECT.