

Package leaflet: Information for the Patient

Rocephin® 1 g Powder for solution for injection/infusion

ceftriaxone (as ceftriaxone sodium)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rocephin is and what it is used for
2. What you need to know before you are given Rocephin
3. How Rocephin is given
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 is an antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Rocephin is used to treat infections of:

- the brain (meningitis).
- the lungs.
- the middle ear.
- the abdomen and abdominal wall (peritonitis).
- the urinary tract and kidneys.
- bones and joints.
- the skin or soft tissues.
- the blood.
- the heart.

It can be given:

- to treat specific sexually transmitted infections (gonorrhoea and syphilis).
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection.
- to treat infections of the chest in adults with chronic bronchitis.
- to treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age.
- to prevent infections during surgery.

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

You must not be given Rocephin if:

- You are allergic to ceftriaxone or any of the other ingredients of this medicine (listed in section 6).
- You have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or

face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly.

- You are allergic to lidocaine and you are to be given Rocephin as an injection into a muscle.

Rocephin 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

Talk to your doctor or pharmacist or nurse before you are given Rocephin if:

- You have recently received or are about to receive products that contain calcium.
- You have recently had diarrhoea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- 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.
- 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”).

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 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.

Children

Talk to your doctor or pharmacist or nurse before your child is administered Rocephin if:

- He/She has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and Rocephin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, 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 breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

The doctor will consider the benefit of treating you with Rocephin against the risk to your baby.

Driving and using machines

Rocephin can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

Rocephin contains sodium

Rocephin 1 g powder for solution for injection/infusion contains 85.4 mg sodium (main component of cooking/table salt) per 1g vial, equivalent to 4.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Rocephin is given

Rocephin is usually given by a doctor or nurse. It can be given as:

- a drip (intravenous infusion) or as an injection directly into a vein or
- into a muscle.

Rocephin is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

The usual dose

Your doctor will decide the correct dose of Rocephin for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given Rocephin depends on what sort of infection you have.

Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):

- 1 to 2 g once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose (up to 4 g once a day). If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.

Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:

- 50-80 mg Rocephin for each kg of the child's body weight once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose up to 100 mg for each kg of body weight to a maximum of 4 g once a day. If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.
- Children with a body weight of 50 kg or more should be given the usual adult dose.

Newborn babies (0-14 days)

- 20 – 50 mg Rocephin for each kg of the child's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

People with liver and kidney problems

You may be given a different dose to the usual dose. Your doctor will decide how much Rocephin you will need and will check you closely depending on the severity of the liver and kidney disease.

If you are given more Rocephin than you should

If you accidentally receive more than your prescribed dose, contact your doctor or nearest hospital straight away.

If you forget to use Rocephin

If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a missed dose.

If you stop using Rocephin

Do not stop taking Rocephin unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Severe allergic reactions (not known, frequency cannot be estimated from the available data)

If you have a severe allergic reaction, tell a doctor straight away.

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 (not known, frequency cannot be estimated from the available data)

If you get a severe skin reaction, tell a doctor straight away.

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).
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting Rocephin treatment for infections with spirochete such as Lyme disease.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- 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.

Uncommon (may affect up to 1 in 100 people)

- 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.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).

Rare (may affect up to 1 in 1,000 people)

- 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 and/or liver, which may cause pain, nausea, vomiting, yellowing of the skin, itching, unusually dark urine and clay-coloured stools.
- 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 any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rocephin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C, keep vial in the outer carton in order to protect from light. Chemical and physical in-use stability of the reconstituted product has been demonstrated for at least 6 hours at or below 25°C or 24 hours at 2-8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not be longer than the times stated above for the chemical and physical in-use stability.

Do not throw away any medicines via wastewater. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rocephin contains

The active substance is ceftriaxone.

Each vial contains 1 g (grams) ceftriaxone as ceftriaxone sodium.
There are no other ingredients.

The displacement volume of 1 g of Rocephin is 0.71 ml in water for injections and 1% lidocaine hydrochloride solution. When adding 10 ml of water for injections, the final concentration of the reconstituted solution is 93.37 mg/ml. When adding 3.5 ml of 1% lidocaine hydrochloride solution, the final concentration of the reconstituted solution is 237.53 mg/ml.

What Rocephin looks like and contents of the pack

Rocephin consists of a powder for solution for injection or infusion

The powder is white to yellowish-orange.

Rocephin is available in packs of 1 vial.

Marketing Authorisation Holder

Roche Products (Ireland) Limited
3004 Lake Drive
Citywest
Naas Road
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Ireland

Manufacturer

Roche Pharma AG
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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Rocephin 1 g Powder for Solution for Injection/Infusion
Italy: Rocefin

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 The following information is intended for healthcare professionals only:

Please refer to the Summary of Product Characteristics for full prescribing information.

Posology

The dose depends on the severity, susceptibility, site and type of infection and on the age and hepato-renal function of the patient.

The doses recommended in the tables below are the generally recommended doses in these indications. In particularly severe cases, doses at the higher end of the recommended range should be considered.

Adults and children over 12 years of age (≥ 50 kg)

Ceftriaxone Dosage*	Treatment frequency**	Indications
1-2 g	Once daily	Community acquired pneumonia
		Acute exacerbations of chronic obstructive pulmonary disease
		Intra-abdominal infections
		Complicated urinary tract infections (including pyelonephritis)
2 g	Once daily	Hospital acquired pneumonia
		Complicated skin and soft tissue infections
		Infections of bones and joints
2-4 g	Once daily	Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
		Bacterial endocarditis
		Bacterial meningitis

* In documented bacteraemia, the higher end of the recommended dose range should be considered.

** Twice daily (12 hourly) administration may be considered where doses greater than 2 g daily are administered.

Indications for adults and children over 12 years of age (≥ 50 kg) that require specific dosage schedules:

Acute otitis media

A single intramuscular dose of Rocephin 1-2 g can be given.

Limited data suggest that in cases where the patient is severely ill or previous therapy has failed, Rocephin may be effective when given as an intramuscular dose of 1-2 g daily for 3 days.

Pre-operative prophylaxis of surgical site infections

2 g as a single pre-operative dose.

Gonorrhoea

500 mg as a single intramuscular dose.

Syphilis

The generally recommended doses are 500 mg-1 g once daily increased to 2 g once daily for neurosyphilis for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on limited data. National or local guidance should be taken into consideration.

Disseminated Lyme borreliosis (early [Stage II] and late [Stage III])
 2 g once daily for 14-21 days. The recommended treatment durations vary and national or local guidelines should be taken into consideration.

Paediatric population

Neonates, infants and children 15 days to 12 years of age (< 50 kg)

For children with bodyweight of 50 kg or more, the usual adult dosage should be given.

Ceftriaxone dosage*	Treatment frequency**	Indications
50-80 mg/kg	Once daily	Intra-abdominal infections
		Complicated urinary tract infections (including pyelonephritis)
		Community acquired pneumonia
		Hospital acquired pneumonia
50-100 mg/kg (Max 4 g)	Once daily	Complicated skin and soft tissue infections
		Infections of bones and joints
		Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
80-100 mg/kg (max 4 g)	Once daily	Bacterial meningitis
100 mg/kg (max 4 g)	Once daily	Bacterial endocarditis

* In documented bacteraemia, the higher end of the recommended dose range should be considered.

** Twice daily (12 hourly) administration may be considered where doses greater than 2 g daily are administered.

Indications for neonates, infants and children 15 days to 12 years (< 50 kg) that require specific dosage schedules:

Acute otitis media

For initial treatment of acute otitis media, a single intramuscular dose of Rocephin 50 mg/kg can be given. Limited data suggest that in cases where the child is severely ill or initial therapy has failed, Rocephin may be effective when given as an intramuscular dose of 50 mg/kg daily for 3 days.

Pre-operative prophylaxis of surgical site infections

50-80 mg/kg as a single pre-operative dose.

Syphilis

The generally recommended doses are 75-100 mg/kg (max 4 g) once daily for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on very limited data. National or local guidance should be taken into consideration.

Disseminated Lyme borreliosis (early [Stage II] and late [Stage III])

50–80 mg/kg once daily for 14-21 days. The recommended treatment durations vary and national or local guidelines should be taken into consideration.

Neonates 0-14 days

Rocephin is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age).

Ceftriaxone dosage*	Treatment frequency	Indications
20-50 mg/kg	Once daily	Intra-abdominal infections
		Complicated skin and soft tissue infections
		Complicated urinary tract infections (including pyelonephritis)
		Community acquired pneumonia
		Hospital acquired pneumonia
		Infections of bones and joints
50 mg/kg	Once daily	Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
		Bacterial meningitis
		Bacterial endocarditis

* In documented bacteraemia, the higher end of the recommended dose range should be considered. A maximum daily dose of 50 mg/kg should not be exceeded.

Indications for neonates 0-14 days that require specific dosage schedules:

Acute otitis media

For initial treatment of acute otitis media, a single intramuscular dose of Rocephin 50 mg/kg can be given.

Pre-operative prophylaxis of surgical site infections

20-50 mg/kg as a single pre-operative dose.

Syphilis

The generally recommended dose is 50 mg/kg once daily for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on very limited data. National or local guidance should be taken into consideration.

Duration of therapy

The duration of therapy varies according to the course of the disease. As with antibiotic therapy in general, administration of ceftriaxone should be continued for 48 - 72 hours after the patient has become afebrile or evidence of bacterial eradication has been achieved.

Older people

The dosages recommended for adults require no modification in older people provided that renal and hepatic function is satisfactory.

Patients with hepatic impairment

Available data do not indicate the need for dose adjustment in mild or moderate liver function impairment provided renal function is not impaired.

There are no study data in patients with severe hepatic impairment (see section 5.2).

Patients with renal impairment

In patients with impaired renal function, there is no need to reduce the dosage of ceftriaxone provided hepatic function is not impaired. Only in cases of preterminal renal failure (creatinine clearance < 10 ml/min) should the ceftriaxone dosage not exceed 2 g daily.

In patients undergoing dialysis no additional supplementary dosing is required following the dialysis.

Ceftriaxone is not removed by peritoneal- or haemodialysis. Close clinical monitoring for safety and efficacy is advised.

Patients with severe hepatic and renal impairment

In patients with both severe renal and hepatic dysfunction, close clinical monitoring for safety and efficacy is advised.

Method of administration

Intramuscular administration

by deep intramuscular injection. Intramuscular injections should be injected well within the bulk of a relatively large muscle and not more than 1 g should be injected at one site.

As the solvent used is lidocaine, the resulting solution should never be administered intravenously. The information in the Summary of Product Characteristics of lidocaine should be considered.

Intravenous administration

Rocephin can be administered by intravenous infusion over at least 30 minutes (preferred route) or by slow intravenous injection over 5 minutes. Intravenous intermittent injection should be given over 5 minutes preferably in larger veins. Intravenous doses of 50 mg/kg or more in infants and children up to 12 years of age should be given by infusion. In neonates, intravenous doses should be given over 60 minutes to reduce the potential risk of bilirubin encephalopathy. Intramuscular administration should be considered when the intravenous route is not possible or less appropriate for the patient. For doses greater than 2 g intravenous administration should be used.

Ceftriaxone is contraindicated in neonates (≤ 28 days) if they require (or are expected to require) treatment with calcium-containing intravenous solutions, including continuous calcium-containing infusions such as parenteral nutrition, because of the risk of precipitation of ceftriaxone-calcium.

For pre-operative prophylaxis of surgical site infections, ceftriaxone should be administered 30-90 minutes prior to surgery.

Instructions for use

The use of freshly prepared solutions is recommended.

For storage conditions of the reconstituted medicinal product, see section 5 “How to store Rocephin”

Rocephin should not be mixed in the same syringe with any drug. The infusion line should be flushed after each administration.

Intramuscular injection: 1 g Rocephin is dissolved in 3.5 ml of 1% Lidocaine Hydrochloride solution. The vial should be gently rolled between the palms, and visually inspected to ensure that resuspension is complete and no particulate material is present. The solution should be administered by deep intramuscular injection. Dosages greater than 1g should be divided and injected at more than one site.

Solutions in Lidocaine should not be administered intravenously.

Intravenous injection: 1 g Rocephin is dissolved in 10 ml of Water for Injections. The vial should be gently rolled between the palms, and visually inspected to ensure that resuspension is complete and no particulate material is present. The injection should be administered over 5 minutes, directly into the vein or via the tubing of an intravenous infusion.

Intravenous infusion: 1 g Rocephin is dissolved in 10 ml of water for injections. The vial should be gently rolled between the palms, and visually inspected to ensure that resuspension is complete and no particulate material is present. The solution should be transferred to 10 ml of one of the following calcium-free infusion fluids: sodium chloride 0.9%, sodium chloride 0.45% + dextrose 2.5%, dextrose 5%, dextrose 10%, dextran 6% in dextrose 5%, hydroxyethyl-starch 6 – 10%, water for injections. The infusion should be administered over at least 30 minutes.

The displacement volume of 1 g of Rocephin is 0.71 ml in water for injections and 1% lidocaine hydrochloride solution. When adding 10 ml of water for injections, the final concentration of the reconstituted solution is 93.37 mg/ml. When adding 3.5 ml of 1% lidocaine hydrochloride solution, the final concentration of the reconstituted solution is 237.53 mg/ml.

Solutions containing Rocephin should not be mixed with or added to solutions containing other agents. In particular, Rocephin is not compatible with calcium-containing solutions such as Hartmann's solution and Ringer's solution. Diluents containing calcium, (e.g. Ringer's solution or Hartmann's solution), should not be used to reconstitute ceftriaxone vials or to further dilute a reconstituted vial for intravenous administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when ceftriaxone is mixed with calcium-containing solutions in the same intravenous administration line. Therefore, ceftriaxone and calcium-containing solutions must not be mixed or administered simultaneously.

Due to ceftriaxone's high solubility, Rocephin is immediately and completely dissolved in the reconstituted solution. The reconstituted solution is a clear solution with a yellow to brownish-yellow color.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.