

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about ROCEPHIN injection. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ROCEPHIN injection against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.** You may need to read it again.

### What ROCEPHIN is used for

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

ROCEPHIN is also used to prevent infections before, during and after surgery.

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

ROCEPHIN belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection or by stopping bacteria from growing.

Your doctor may have prescribed ROCEPHIN for another reason. **Ask your doctor if you have any questions why ROCEPHIN has been prescribed for you.**

This medicine is available only with a doctor's prescription.

ROCEPHIN is not addictive.

### Before you are given ROCEPHIN

#### When you must not be given it

**Do not use ROCEPHIN if:**

- **you have had an allergic reaction to ROCEPHIN, other cephalosporins or any of the ingredients listed at the end of this leaflet**

Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, dry skin, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles.

- **you have had a serious allergic reaction to penicillins.** You may have an increased chance of being allergic to ROCEPHIN if you are allergic to penicillins.

**In newborns, ROCEPHIN should not be given if they require (or are expected to require) treatment with calcium containing intravenous solutions, including parenteral nutrition (intravenous nutrition) .**

**ROCEPHIN should not be given to preterm newborns or newborns with certain liver disorders.**

**If you are not sure if you should start using ROCEPHIN, contact your doctor.**

#### Before you are given it

**Your doctor must know about all the following before you are given ROCEPHIN.**

**You must tell your doctor if:**

1. **you have any type of allergic reaction to penicillin medicines**  
You may have an increased chance of being allergic to ROCEPHIN if you are allergic to penicillins.

2. **you have had an allergy or over-reaction to lignocaine or other anaesthetic drugs**

These substances may be used to dissolve ROCEPHIN before administration.

3. **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**

4. **you have or have ever had any medical conditions including:**

- kidney disease
- bowel conditions e.g. inflammation of the large bowel.
- diarrhoea associated with previous use of antibiotics
- previous infection of your intestine with a bacteria called *Clostridium difficile*.

5. **you are pregnant, intend to become pregnant, are breast feeding or plan to breast feed**

Your doctor will discuss the risks and benefits of using ROCEPHIN during pregnancy or when breast-feeding.

**If you have not told your doctor about any of the above, tell them before you are given ROCEPHIN.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop. Some medicines and ROCEPHIN may interfere with each other. These include:**

- chloramphenicol, vancomycin, aminoglycosides, medicines used to treat infections
- fluconazole, a medicine used to treat fungal infections
- amsacrine, a medicine used to treat cancer

These medicines may be affected by ROCEPHIN, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

**Talk to your doctor about the need for an additional method of contraception while using ROCEPHIN.**

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with ROCEPHIN.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given ROCEPHIN.

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### **How ROCEPHIN is given**

ROCEPHIN can be given in two ways:

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

**ROCEPHIN must only be given by a doctor or nurse.**

**ROCEPHIN should not be mixed or administered with calcium-containing solutions, even via different infusion lines.**

Your doctor will decide what dose and for how long you will receive ROCEPHIN. This depends on your infection and other factors, such as your weight. For most infections, ROCEPHIN is usually given once a day. The length of treatment usually is 4-14 days.

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

If too much ROCEPHIN is given, you may experience symptoms such as skin reactions, chills, diarrhoea, stomach upsets, headache or dizziness.

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### **While you are using ROCEPHIN**

#### ***Things you must do***

**If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.**

**If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after ROCEPHIN has been stopped.**

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

**If you get a sore or furry white mouth or tongue while using or soon after stopping ROCEPHIN, tell your doctor. Also tell your**

**doctor if you get vaginal itching or discharge.**

This may mean that you have a fungal infection called thrush. Sometimes the use of ROCEPHIN allows fungi to grow and the above symptoms to occur. ROCEPHIN does not work against fungi.

**If you become pregnant while using ROCEPHIN, tell your doctor.**

**If you have to test your urine for sugar while you are being given ROCEPHIN, make sure your doctor knows which type of test you use.**

ROCEPHIN may affect the results of some of these tests.

**If you have any blood tests tell your doctor you are being given ROCEPHIN.**

Complete blood counts should be done at regular intervals as ROCEPHIN may affect the results of some blood tests.

**Tell all doctors, dentists and pharmacists who are treating you that you are using ROCEPHIN.**

#### ***Things you must not do***

**Do not give ROCEPHIN to anyone else even if they seem to have the same condition as you.**

**Do not use ROCEPHIN to treat other complaints unless your doctor says so.**

#### ***Things to be careful of***

**Be careful driving or operating machinery until you know how ROCEPHIN affects you.**

ROCEPHIN generally does not cause any problems with your ability to drive or operate machinery. However, as with many other medicines, ROCEPHIN may cause dizziness in some people.

## Storage

ROCEPHIN will be stored in the pharmacy or on the ward. The powder for injection is kept in a cool dry place where the temperature stays below 30 °C.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ROCEPHIN.**

ROCEPHIN helps most people with infections but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

### **While using it**

**Tell your doctor if you notice any of the following and they worry you:**

- white, furry, sore tongue and mouth (oral thrush)
- sore and itchy vagina and/or discharge (vaginal thrush)
- a hard lump, swelling, pain or tenderness at the injection site
- diarrhoea, feeling sick, vomiting
- altered sense of taste
- headache, dizziness
- fast or irregular heart beat.

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

- severe skin rash, itching or hives
- red, peeling or dry skin

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes
- severe diarrhoea (that may contain blood and mucous), stomach pain, and fever.

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

### **After finishing it**

**Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with ROCEPHIN:**

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea
- raised temperature (fever) in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

**Do not take any diarrhoea medicine without first checking with your doctor.**

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## Product Description

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### **What ROCEPHIN looks like**

Rocephin is available as a white to yellowish-orange powder. It is reconstituted before injection into a vein or muscle.

### **Ingredients**

ROCEPHIN does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

**Active ingredients** - ceftriaxone as the sodium salt

- each 1 gram ROCEPHIN vial contains 1 gram ceftriaxone
- each 2 gram ROCEPHIN vial contains 2 gram ceftriaxone.

ROCEPHIN 1 gram and 2 gram come in packs of 1 vial.

### **Distributor**

ROCEPHIN is distributed by:

Roche Products Pty Limited  
ABN 70 000 132 865  
4 - 10 Inman Road  
Dee Why NSW 2099  
AUSTRALIA

Customer enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

1 gram vial



- AUST R 13762
- 2 gram vial
- AUST R 13763

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