

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

RANCEPH 250 CAPSULES

RANCEPH 500 CAPSULES

Cefalexin monohydrate equivalent to cefalexin anhydrous 250 mg

Cefalexin monohydrate equivalent to cefalexin anhydrous 500 mg

RANCEPH 250 CAPSULES:

Contains sugar: Lactose 17 mg per capsule

RANCEPH 500 CAPSULES:

Contains sugar: Lactose 34 mg per capsule

Read all of this leaflet carefully before you start taking RANCEPH CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or your pharmacist, nurse or other health provider.
- RANCEPH CAPSULES have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What RANCEPH CAPSULES is and what it is used for

RANCEPH CAPSULES contain cefalexin, as the active ingredient, which belongs to a class of antibiotics called 'cefalosporins'.

Cefalexin works by destroying certain bacteria that cause infection.

RANCEPH CAPSULES are used to treat following infections caused by bacteria that can be killed by cefalexin:

- Respiratory tract (lung and airways) infections
- Middle ear infections (otitis media)
- Skin and soft tissue infections
- Infections of the reproductive organs and urinary tract including acute infection of the prostate gland (prostatitis)
- Dental infections.

2. What you need to know before you take RANCEPH CAPSULES

Do not take RANCEPH CAPSULES:

- if you are allergic (hypersensitive) to cefalosporins (similar group of antibiotics).
- if you are hypersensitive to any of the other ingredients of RANCEPH CAPSULES.
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with RANCEPH CAPSULES :

Check with your doctor or pharmacist before taking RANCEPH CAPSULES:

- if you develop diarrhoea. Inflammation of the colon (pseudomembranous colitis). Such condition may be life-threatening, care should be taken. Your doctor may discontinue RANCEPH CAPSULES.
- if you have kidney problems.

- if you need a laboratory investigation such as blood test or urine test, do inform your doctor about the medicine you are taking. This is because RANCEPH CAPSULES can affect the results of these types of tests.

Other medicines and RANCEPH CAPSULES

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

(This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following:

- Probenecid (used for gout)
- Diuretics (water tablets) such as furosemide
- Other antibiotics, especially gentamicin or tobramycin

RANCEPH CAPSULES with food and drink

RANCEPH CAPSULES may be taken before, during or after your meals. Swallow the capsules whole with water.

Pregnancy, breast-feeding and fertility

You should tell your doctor if you are pregnant or planning to become pregnant or breastfeeding.

The safety of RANCEPH CAPSULES in pregnancy and breastfeeding has not been established.

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

Driving and using machines

RANCEPH CAPSULES may cause dizziness, drowsiness or confusion. You should not drive or operate machinery until you know how RANCEPH CAPSULES affect you.

RANCEPH CAPSULES contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

How to take RANCEPH CAPSULES

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

Always take RANCEPH CAPSULES exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow the capsules whole with water.

Your doctor will decide the most appropriate dose for you, based on the nature and severity of your infection.

Adults

The usual daily dose ranges from 1g to 4g a day, in divided doses. The usual adult dosage is 250 mg every 6 hours or 500 mg every 12 hours.

If you are suffering from more severe infections, your doctor will advise you larger doses. If the daily doses required by you depending on the severity of infection is more than 4 g than your doctor will recommend injectable antibiotics.

Duration of treatment

Your doctor will advise the duration of therapy. In the treatment of certain bacterial infections of the throat and skin (beta-haemolytic streptococcal infections), RANCEPH CAPSULES should be administered for at least 10 days.

Elderly and patients with abnormal renal function

You should take the normal adult dose, unless you have severe kidney problems.

Children

Your doctor will calculate the correct dose, depending on the child's weight.

The recommended daily dose is 25 mg/kg to 50 mg/kg. Your doctor will advise you to split the dose in smaller amount which will be given every 6 hours.

The use of the capsules is not feasible in young children.

If you take more RANCEPH CAPSULES than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet, the pack or any capsules with you.

If you forget to take RANCEPH CAPSULES

If you miss a dose, take it as soon as you remember. If it is almost time to take the next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with RANCEPH CAPSULES is stopped:

Do not stop taking your medicine without telling your doctor, even if you feel better.

If you have any further questions on the use of RANCEPH CAPSULES, ask your doctor or pharmacist.

3. Possible side effects

RANCEPH CAPSULES can have side effects.

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

If any of the following happen, stop taking RANCEPH CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital.

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin. These are the signs of hypersensitivity reaction.
- reactions resembling serum sickness–like reactions (skin rash accompanied by fever, swelling, skin rash, enlargement of the lymph nodes) and anaphylaxis (sudden life-threatening allergic reaction).
- serious peeling or blistering of the skin.
- severe diarrhoea (which may contain blood or mucous) along with stomach cramps. These may be manifestation of pseudomembranous colitis (inflammation of colon).

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to RANCEPH CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- changes to blood counts which may show up as bruising or a very tired feeling. You will need a blood test to confirm this.
- headache.
- feeling sick (nausea), being sick (vomiting), diarrhoea.

Less frequent side effects:

- dizziness, drowsiness and tiredness (fatigue).
- damage to your kidneys or liver which can be detected by a blood and/or urine test.
- loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine. (These may be manifestation of inflammation of the liver caused by RANCEPH CAPSULES).
- fits, seizures and confusion particularly in patients with damaged kidney.

- vaginal itching or irritation (thrush).
- stomach cramps or spasms.

There may be changes in the results of certain laboratory tests:

- abnormal liver function tests. Increase in levels of liver enzymes.
- positive results of a type of blood test called Coombs' test.
- a false-positive reaction for glucose in the urine may occur with some tests.

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, pharmacist 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 RANCEPH CAPSULES.

4. How to store RANCEPH CAPSULES

Store at or below 25 °C, protected from moisture.

KEEP OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What RANCEPH CAPSULES contains

The active substance in RANCEPH CAPSULES is cefalexin.

RANCEPH 250 CAPSULES:

Each capsule contains cefalexin monohydrate equivalent to cefalexin anhydrous 250 mg.

RANCEPH 500 CAPSULES:

Each capsule contains cefalexin monohydrate equivalent to cefalexin anhydrous 500 mg.

The other ingredients:

RANCEPH 250 CAPSULES: Lactose, magnesium stearate.

RANCEPH 500 CAPSULES: Lactose, magnesium stearate.

What RANCEPH CAPSULES looks like and contents of the pack

RANCEPH 250 CAPSULES:

Dark green/white self-locked, hard gelatin capsules of size '2' imprinted with 'RX656' in black edible ink containing a white to off-white granular powder/pellet.

RANCEPH 500 CAPSULES:

Dark green/light green self-locked, hard gelatin capsules of size '0' imprinted with 'RX657' in black edible ink containing a white to off-white granular powder/pellet.

Contents of the pack:

RANCEPH 250 CAPSULES:

Carton containing 2 x 10 capsules in blister strips.

Carton containing 10 x 10 capsules in blister strips.

RANCEPH 500 CAPSULES:

Carton containing 2 x 10 capsules in blister strips.

Carton containing 10 x 10 capsules in blister strips.

Holder of Certificate of Registration

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Registration numbers

RANCEPH 250 CAPSULES: 30/20.1.1/0334

RANCEPH 500 CAPSULES: 30/20.1.1/0335

Ranceph 250 Capsules:

Namibia: NS2; Reg No.: 04/20.1.1/0610

Botswana: S2; Reg No.: BOT0901582

Ranceph 500 Capsules:

Namibia: NS2; Reg No.: 04/20.1.1/0611

Botswana: S2; Reg No.: BOT0901583