PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

RANCEPH SUSPENSION 125 mg/5 ml

RANCEPH SUSPENSION 250 mg/5 ml

Cefalexin monohydrate equivalent to cefalexin anhydrous 125 mg/5 ml

Cefalexin monohydrate equivalent to cefalexin anhydrous 250 mg/5 ml

RANCEPH SUSPENSION 125 mg/5 ml:

Contains sugar: 2,33 g per 5 ml

Contains sodium: 5 mg per 5 ml

RANCEPH SUSPENSION 125 mg/5 ml:

Contains sugar: 2,19 g per 5 ml

Contains sodium: 5 mg per 5 ml

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor,–pharmacist, nurse or other health provider.
- RANCEPH SUSPENSION has 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 SUSPENSION is and what it is used for
2. What you need to know before you take RANCEPH SUSPENSION
3. How to take RANCEPH SUSPENSION
4. Possible side effects
5. How to store RANCEPH SUSPENSION
6. Contents of the pack and other information

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

RANCEPH SUSPENSION, belongs to a class of antibiotics called 'cefalosporins'.

Cefalexin works by destroying certain bacteria that cause infection.

RANCEPH SUSPENSION is 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 SUSPENSION

Do not take RANCEPH SUSPENSION:

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

Warnings and precautions

Take special care with RANCEPH SUSPENSION:

Check with your doctor or pharmacist before giving or taking RANCEPH SUSPENSION:

- 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 SUSPENSION.
- 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 SUSPENSION can affect the results of these types of tests.

Other medicines and RANCEPH SUSPENSION

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 SUSPENSION with food and drink

RANCEPH SUSPENSION may be taken before, during or after your meals

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 SUSPENSION 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 SUSPENSION.

Driving and using machines

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

RANCEPH SUSPENSION contains sugar

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

RANCEPH SUSPENSION contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take RANCEPH SUSPENSION

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

Always use RANCEPH SUSPENSION exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

Adults

The usual daily dose ranges from 1 g to 4 g 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. The usual course of treatment is 7 days, ranging from 5 to 10 days. In the treatment of certain bacterial infections of the throat and skin (beta-haemolytic streptococcal infections), RANCEPH SUSPENSION 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.

Adults who are not able to take capsules may be given RANCEPH SUSPENSION.

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.

Directions for mixing

Add 67 ml water in two portions to the dry mixture in the bottle. Shake well after each addition.

If you take more RANCEPH SUSPENSION 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 SUSPENSION

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 SUSPENSION is stopped:

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

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

4. Possible side effects

RANCEPH SUSPENSION can have side effects.

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

If any of the following happen, stop taking RANCEPH SUSPENSION 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 SUSPENSION. 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 SUSPENSION.)
- 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 SUSPENSION.

5. How to store RANCEPH SUSPENSION

Store in well closed containers at or below 25 °C, protected from moisture. After reconstitution, the product must be stored at 2-8°C in a refrigerator. The prepared suspension should be consumed within 10 days of preparation. Discard any unused portion of the reconstituted suspension after 10 days. KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What RANCEPH SUSPENSION contains

The active substance in RANCEPH SUSPENSION is cefalexin.

RANCEPH SUSPENSION 125 mg/5 ml: Each 5 ml of constituted suspension contains cefalexin monohydrate equivalent to 125 mg cefalexin anhydrous.

RANCEPH SUSPENSION 250 mg/5 ml: Each 5 ml of constituted suspension contains cefalexin monohydrate equivalent to 250 mg cefalexin anhydrous.

The other ingredients:

RANCEPH SUSPENSION 125 mg/5 ml: Colloidal anhydrous silica, orange flavour, pineapple dry flavour, sodium benzoate, sugar, sunset yellow supra and xanthan gum.

RANCEPH SUSPENSION 250 mg/5 ml: Colloidal anhydrous silica, orange flavour, pineapple dry flavour, sodium benzoate, sugar, sunset yellow supra and xanthan gum.

What RANCEPH SUSPENSION looks like and contents of the pack

RANCEPH SUSPENSION 125 mg/5 ml:

Off-white powder forming an orange syrupy suspension on constitution with water. The resulting suspension has a characteristic flavour of orange and pineapple.

RANCEPH SUSPENSION 250 mg/ 5ml:

Off-white powder forming an orange syrupy suspension on constitution with water. The resulting suspension has a characteristic flavour of orange and pineapple

Contents of the pack:

RANCEPH SUSPENSION 125 mg/5 ml: HDPE bottle of 100 ml

RANCEPH SUSPENSION 250 mg/5 ml: HDPE bottle of 100 ml

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

This leaflet was last revised in

10 August 2023

Registration numbers

RANCEPH SUSPENSION 125 mg/5 ml: 32/20.1.1/0214

RANCEPH SUSPENSION 250 mg/5 ml: 32/20.1.1/0215

Ranceph Suspension 125 mg/5 ml:

Namibia: NS2 Reg. No: 04/20.1.1/1292

Botswana: S2 Reg. No: BOT0500802

Ranceph Suspension 250 mg/5 ml:

Namibia: NS2 Reg. No: 04/20.1.1/1293