Professional Information

SCHEDULING STATUS:

S4

1. NAME OF THE MEDICINE

RANCEPH SUSPENSION 125 mg/5 ml

RANCEPH SUSPENSION 250 mg/5 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

RANCEPH SUSPENSION 125 mg/5 ml

Each 5 ml of constituted suspension contains:

Cefalexin monohydrate	
equivalent to cefalexin anhydrous	125 mg
Sodium benzoate (as preservative)	0,1 % *m/v*

Contains sugar: 2,33 g per 5 ml

Contains sodium: 5 mg per 5 ml

RANCEPH SUSPENSION 250 mg/ 5ml

Each 5 ml of constituted suspension contains:

Cefalexin monohydrate	
equivalent to cefalexin anhydrous	250 mg
Sodium benzoate (as preservative)	0,1 % *m/v*

Contains sugar: 2,19 g per 5 ml

Contains sodium: 5 mg per 5 ml

3. PHARMACEUTICAL FORM

Suspension

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RANCEPH SUSPENSION is indicated for the treatment of the following infections caused by susceptible micro-organisms:

- Respiratory tract infections caused by *Streptococcus pneumonia* and group A ß-*haemolytic streptococci*.
- Otitis media due to Streptococcus pneumonia, H. influenzae, staphylococci, streptococci and N. catarrhalis.
- Skin and soft tissue infections caused by *staphylococci* and/or *streptococci*.
- Genito-urinary tract infections, including acute prostatitis caused by *E. coli*, *P. mirabilis* and *Klebsiella*.
- Dental infections caused by *staphylococci* and/or *streptococci*.

Appropriate culture and susceptibility studies should be performed to determine susceptibility of causative organism to cefalexin. Renal function studies should be performed when indicated.

4.2 Posology and method of administration

Posology

Adults: The adult dosage ranges from 1-4 g daily in divided doses. The usual adult dosage is 250 mg every 6 hours. For skin and soft tissue infections, streptococcal pharyngitis and mild uncomplicated urinary tract infections, the usual dosage is 250 mg every 6 hours, or 500 mg every 12 hours.

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

For more severe infections or those caused by less susceptible organisms, larger doses may be needed. If daily doses of RANCEPH SUSPENSION greater than 4 grams are required, parenteral cephalosporins, in appropriate doses, should be considered.

The elderly and patients with impaired renal function: As for adults. Reduce dosage if renal function is markedly impaired.

Children: The usual recommended dosage for children is 25mg/kg/day to 50mg/kg/day in divided doses every six hours.

In the treatment of beta-haemolytic streptococcal infections, a therapeutic dose should be administered for at least 10 days.

Directions for mixing

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

Method of administration

Oral administration.

4.3 Contraindications

RANCEPH SUSPENSION is contra-indicated in:

- **RANCEPH SUSPENSION** should not be used in patients with known hypersensitivity to the cefalexin or any of the excipients of **RANCEPH SUSPENSION** (listed in section 6.1).
- Patients with known allergy to the cefalosporin group of antibiotics. (See Section 4.4)

- Pregnancy and lactation (see Section 4.6).

4.4 Special warnings and precautions for use

Before therapy with RANCEPH SUSPENSION is started, careful enquiry should be made concerning previous hypersensitivity reactions to cephalosporins, penicillins or other medicine. RANCEPH SUSPENSION should be administered with caution to penicillin-sensitive patients. There is evidence of cross-allergenicity between the penicillins and cefalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both.

The diagnosis of pseudomembranous colitis must be considered in patients who develop diarrhoea in association with its use. Such colitis may be life-threatening and appropriate measures should be taken, including discontinuation of RANCEPH SUSPENSION.

RANCEPH SUSPENSION should be administered with caution in the presence of impaired renal function; dosage reduction may be necessary. Renal and haematological status should be monitored especially during prolonged and high-dose therapy.

RANCEPH SUSPENSION may interfere with the Jaffé method of measuring creatinine concentrations and may produce falsely high values; this should be borne in mind when measuring renal function.

Positive direct Coombs' (antiglobulin) have been reported during treatment with the cefalosporin antibiotics and these can interfere with blood cross-matching.

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.

4.5 Interaction with other medicines and other forms of interaction

The concomitant use of nephrotoxic medicines such as the aminoglycosides gentamicin and tobramycin may increase the risk of kidney damage with RANCEPH SUSPENSION. There is also evidence for enhanced nephrotoxicity with the loop diuretic furosemide.

The renal excretion of RANCEPH SUSPENSION is inhibited by probenecid.

There may be antagonism between RANCEPH SUSPENSION and bacteriostatic antibacterials.

RANCEPH SUSPENSION may decrease the efficacy of oestrogen containing contraceptives.

4.6 Fertility, pregnancy and lactation

The safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

RANCEPH SUSPENSION may cause dizziness or drowsiness. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility is known.

RANCEPH SUSPENSION contains sugar. Patients with rare hereditary problems of fructose intolerance insufficiency should not take RANCEPH SUSPENSION.

4.8 Undesirable effects

System Organ Class	Frequent	Less frequent
Blood and the lymphatic system disorders	**Eosinophilia.**	**Haemolytic anaemia, neutropaenia and thrombocytopenia.**
Immune system disorders		**Hypersensitivity reactions, including skin rashes, urticaria, eosinophilia, fever,**

		reactions resembling serum sickness, and anaphylaxis.
Nervous system disorders	**Headache.**	**Dizziness and drowsiness. Convulsions and confusion have been associated with high doses, especially in patients with renal impairment.**
Gastro-intestinal disorders	**Nausea, vomiting and diarrhoea.**	**Abdominal cramps, pseudomembranous colitis and overgrowth of non-susceptible organisms have been reported.**
Hepato-biliary disorders		**Hepatitis and cholestatic jaundice.**
Renal and urinary disorders		**Nephrotoxicity, acute renal tubular necrosis, acute interstitial nephritis**

Reproductive system and breast disorders		**Vulval candidiasis.**
General disorders and administration site conditions		**Fatigue.**
Investigations		**Positive response to the Coombs' (antiglobulin) test; transient increases in liver enzyme values.**

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See Section 4.8.

Treatment is symptomatic and supportive. Cefalexin is removed by haemodialysis and peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 20.1.1 Broad and medium spectrum antibiotics. Pharmacotherapeutic group: Antibacterials for systemic use, First-generation cephalosporins.

ATC code: J01DB

Cefalexin is a broad spectrum bactericidal antibiotic. It acts by inhibiting bacterial cell-wall synthesis. Cefalexin is active against Gram positive and Gram negative organisms *in vitro*. Most strains of *enterococci* (*Streptococcus faecalis*) and a few strains of *staphylococci* are resistant to cefalexin. It is not active against most strains of *Enterobacter* species, *P. morganii* and *P. vulgaris*. It has no activity against *Pseudomonas* or *Herellea* species. When tested by *in vitro* methods, *staphylococci* exhibit cross-resistance between cefalexin and methicillin-type antibiotics.

In vitro sensitivity does not necessarily imply *in vivo* efficacy.

5.2 Pharmacokinetic properties

It is rapidly absorbed from the upper gastro-intestinal tract, giving peak levels at 1 hour and following food at 2 hours. Following doses of 250 mg and 500 mg in adults average serum levels of about 9 and 18 mcg per ml respectively were obtained at one hour.

Over 90 % is recovered unchanged in urine within 8 hours. Peak urine concentrations are 1000 mcg per ml during this period following a 250 mg dosage of cefalexin.

The serum half-life of cefalexin is 0,9 to 1,2 hours but is prolonged in neonates. In uremic patients the half-life may increase to 5-30 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

RANCEPH SUSPENSION 125 mg/5 ml

- Colloidal anhydrous silica,
- orange flavour,
- pineapple dry flavour,
- sodium benzoate,
- sugar,
- sunset yellow supra,
- xanthan gum.

RANCEPH SUSPENSION 250 mg/5 ml

- Colloidal anhydrous silica,
- orange flavour,
- pineapple dry flavour,
- sodium benzoate,
- sugar,
- sunset yellow supra,
- xanthan gum.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

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

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

6.6 Special precautions for disposal and other handling

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

No special requirements for disposal.

7. HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD.

14 LAUTRE ROAD

STORMILL EXT.1

ROODEPOORT 1724

SOUTH AFRICA

8. REGISTRATION NUMBER(S)

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

Botswana: S2 Reg. No: BOT0500801

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 July 1999

10. DATE OF REVISION OF THE TEXT

10 August 2023