PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RANCLAV 1 g Film-coated tablets

Sugar free

Read all of this leaflet carefully before you start taking RANCLAV 1 g tablets

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RANCLAV 1 g 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 RANCLAV 1g is and what it is used for

RANCLAV 1g tablets (combination of amoxicillin and clavulanic acid) are used for the treatment of a wide range of bacterial infections. Some of these infections are:

- Chest infections such as bronchitis and pneumonia;
- Infections of sinuses (sinusitis) and the ear (otitis media);
- Skin and soft tissue infections
- Urinary tract infections

2. What you need to know before you take or give RANCLAV 1g

Do not take RANCLAV 1 g:

- If you are hypersensitive (allergic) or have previously had an allergic reaction to amoxicillin, or to other beta lactam antibiotics (e.g., penicillin, ampicillin, or cephalosporin such as cephalexin, cefadroxil) or to clavulanic acid or to any of the other ingredients of RANCLAV 1g (listed in section 6). (Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty in breathing and swelling of the face, lips, tongue and throat)
- If you have had liver problems (yellowing of skin and whites of eyes) with amoxicillin/ clavulanate combination at any time in the past
- If you are pregnant.

Warnings and precautions

Take special care with RANCLAV 1 g

- If you are breast feeding currently
- If you have a condition commonly known as glandular fever (also called infectious mononucleosis)
- If you have been diagnosed to have lymphatic leukaemia (a type of blood cancer)
- If you have problems with your kidney(s) and/ or liver

Please consult your doctor, even if these statements were applicable to you at any time in the past.

If you need a laboratory investigation such as blood test or urine test, do inform your doctor about the medicines you are taking.

Do not consume alcoholic beverages while taking this medicine (and several days afterwards) until you have discussed their use with your doctor.

Other medicines and RANCLAV 1 g

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Care is needed if you are taking the following medicines along with RANCLAV 1 g:

- Probenecid (medicine for treating joint problems and along with certain other antibiotics for treating severe infections)
- Allopurinol (medicine for treating joint problems)
- Hormonal contraceptives pills
- Blood thinning medicines or anticoagulants (e.g. warfarin)
- Methotrexate (medicines for treating some kinds of cancer or other conditions such as severe psoriasis and rheumatoid arthritis

Taking RANCLAV 1 g with food or drink:

For best results, you may take RANCLAV 1 g at the start of a meal. Swallow the tablet whole with a glass of water.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast feeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The safety of this medicine for use during pregnancy has not been established. Do not take this medicine if you are pregnant. Take special care if you are breastfeeding.

There is no fertility data available.

Driving and using machines

RANCLAV 1 g can cause side effects that affect your ability to drive.

Do not drive or use machines unless you are sure you are not affected.

3. How to take RANCLAV 1 g

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

Always take RANCLAV 1 g exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one RANCLAV 1 g tablets taken twice daily.

Swallow the tablet(s) whole with a glass of water. For best results, you may take RANCLAV 1 g at the start of a meal.

Your dose may be different in case you have kidney and/or liver problems.

Your doctor will tell you how long your treatment with RANCLAV 1 g will last.

Take your medicine as directed and for as long as directed. Do not stop treatment early even if you feel better.

If you have the impression that the effect of RANCLAV 1 g is too strong or too weak tell your doctor or pharmacist.

If you forget to take RANCLAV 1 g

If you forget to take RANCLAV 1 g at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you take more RANCLAV 1 g than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet or some medicine with you so your doctor will know what you have taken.

4. Possible side effects

RANCLAV 1 g can have side effects.

Not all side- effects reported for RANCLAV 1 g are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RANCLAV 1 g, please consult your health care provider for advice.

If any of the following happens, stop taking RANCLAV 1 g and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, lips, mouth, or throat which may cause difficulty in swallowing or breathing, ankles, hands / feet, fainting with muscle and joint pains, and fever
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

- Severe skin reactions such as blisters in a circle with central crusting or like a string of pearls (linear IgA disease), sores or ulceration

These are very serious side effects. If you have them, you may have had a serious reaction to RANCLAV 1 g. You may need urgent medical attention or hospitalisation.

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

- Severe diarrhoea (which may contain blood or mucous) along with stomach cramps
- Convulsions
- Yellowing of skin and whites of eyes, high coloured urine or clay coloured stools, with decreased appetite, abdominal pain
- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia
- Change in regular urine output with cloudy urine
- Mental status changes (drowsiness, confusion)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache and dizziness
- Nausea (feeling sick), vomiting (being sick), indigestion, abnormal taste, stomach ache, diarrhoea, sore tongue and mouth, black discolouration of tongue, discolouration of teeth, white patches inside the mouth or on the tongue (oral thrush), altered taste
- Vaginal discharge and itching
- Tiredness, hot flushes
- skin rashes, urticaria and erythema multiforme
- Allergic reaction leading to repetitive vomiting that occurs 1-4 hours after taking the medicine. Further symptoms include abdominal pain, lethargy, diarrhoea and low blood pressure.

Less frequent side effects:

- Prolongation of bleeding time and prothrombin time; blood clots
- Reversible hyperactivity
- Frequent, intense urge to urinate, with lower back pain and/ or fever & chills (this can indicate that you have crystals in your urine leading to acute renal injury)
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)
- Severe and on-going pain in the stomach area this could be a sign of acute pancreatitis

There may be changes in the results of certain laboratory tests

- Abnormal liver function tests
- Increased numbers of a type of blood cell called eosinophils
- Increased numbers of platelets

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RANCLAV 1 g.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

5. How to store RANCLAV 1 g

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package.
- Protected from light/moisture.

- Do not use after the expiry date stated on the label/carton.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RANCLAV 1 g contains

The active substances are:

Amoxicillin trihydrate

equivalent to amoxicillin 875mg

Clavulanate potassium

equivalent to clavulanic acid 125mg.

The other ingredients are :Basic butylated methacrylate copolymer, colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, Opadry white (coating agent), povidone, sodium starch glycollate,

What RANCLAV 1 g looks like and contents of the pack

White, film coated, capsule shaped tablets debossed with 'RX509' on one side and a scoreline on the other.

Carton contains 10 tablets packed in a PVC/PVdC blister pack within a 4-layered laminated bag containing a desiccant sachet.

PVC/PVdC blister pack in a 4-layered laminated bag:

Clear PVC film coated with PVdC on the inner side with the lidding of hard tempered, aluminium foil coated with heat seal lacquer on the inner side.

One blister to be put into a 4-layered laminated bag containing a desiccant sachet.

The structure of the four layered laminated bag is as follows: Polyester film/ Aluminium foil/ Polyester film/ Polyethylene.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

Tel: +27(0) 12 643 2000

This leaflet was last revised in

14 April 2025

Registration number

A40/20.1.2/0568

Botswana: S2 Reg. no.: BOT0701095

Namibia: NS2 Reg. no.: 07/20.1.2/0182