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

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 "**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 RANCLAV 1 g.

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.

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- 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

This leaflet was last revised in

To be advised

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A40/20.1.2/0568

Botswana: S2 Reg. no.: BOT0701095

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

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

RANCLAV 1 g Filmbedekte tablette

Suikervry

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om RANCLAV 1 g tablette te neem

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief vir jou dokter, apteker, verpleegkundige of ander gesondheidsorgdeskundige as jy verdere vrae het.
- RANCLAV 1 g is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit mag skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat is RANCLAV 1 g en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy RANCLAV 1 g neem
3. Hoe om RANCLAV 1 g te neem
4. Moontlike newe-effekte
5. Hoe om RANCLAV 1 g te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is RANCLAV 1g en waarvoor word dit gebruik

RANCLAV 1g tablette (kombinasie van amoksisillien en klavulaansuur) word gebruik vir die behandeling van ‘n wye reeks van bakteriële infeksies. Sommige van hierdie infeksies is:

- Borskasinfeksies soos brongitis en longontsteking;
- Infeksies van die sinusse (sinusitis) en die oor (otitis media);
- Vel- en sagte weefselinfeksies
- Urienweginfeksies

2. Wat jy moet weet voordat jy RANCLAV 1g neem

Moenie RANCLAV 1 g neem nie:

- As jy hipersensitief (allergies) is of voorheen ‘n allergiese reaksie gehad het teenoor amoksisillien, of teenoor enige beta-laktaam antibiotikum (bv. penisillien, ampisillien, of kefalosporien soos kefaleksien, kefadroksiel) of teenoor klavulaansuur of teenoor enige ander van die bestanddele van RANCLAV 1g (gelys in afdeling 6). (Sommige van die simptome van ‘n allergiese reaksie kan veluitslag, gejeuk, probleme met asemhaling en swelling van die gesig, lippe, tong en keel insluit)
- As jy lewerprobleme op enige tyd in die verlede gehad het (vergeling van die vel en wit van die oë) met die kombinasie van amoksisillien/klavulanaat
- As jy swanger is.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met RANCLAV 1 g:

- As jy tans borsvoed
- As jy ‘n toestand het wat algemeen bekend staan as klierkoors (ook aansteeklike mononukleose genoem)
- As jy gediagnoseer is om limfatiese leukemie te hê (‘n tipe bloedkanker)
- As jy probleme met jou nier(e) en/of lewer het

Konsulteer asseblief jou dokter, selfs as hierdie stellings op enige tydstip in die verlede op jou van toepassing was. As jy laboratoriumondersoeke nodig het, soos bloedtoetse of urinetoetse, moet jy jou dokter inlig oor die medikasie wat jy gebruik.

Moenie alkoholiese drankies nuttig terwyl jy hierdie medisyne gebruik nie (en vir verskeie dae daarna) totdat jy die gebruik met jou dokter bespreek het nie.

Ander medisyne en RANCLAV 1 g

Lig jou gesondheidsorgvoorsiener altyd in as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in).

Versigtigheid moet toegepas word as jy die volgende medisyne saam met RANCLAV 1 g neem:

- Probenesied (medisyne om gewrigsprobleme te behandel en saam met sekere ander antibiotika vir die behandeling van ernstige infeksies)
- Allopurinol (medisyne vir die behandeling van gewrigsprobleme)
- Hormonale voorbehoedpille

- Bloedverdunningsmedisyne of antikoagulante (bv. warfarien)

Neem van RANCLAV 1 g saam met voedsel en drinkgoed:

Vir die beste resultate kan jy RANCLAV 1 g aan die begin van ‘n maaltyd neem. Sluk die tablet heel in met ‘n glas water.

Swangerskap, borsvoeding en fertiliteit

As jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, moet jy asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Die veiligheid van hierdie medisyne vir gebruik tydens swangerskap is nie vasgestel nie, Moenie hierdie medisyne gebruik as jy swanger is nie. Tref spesiale voorsorg as jy borsvoed.

Daar is geen fertiliteitsdata beskikbaar nie.

Bestuur en gebruik van masjinerie

RANCLAV 1 g kan newe-effekte veroorsaak wat jou vermoë om te bestuur kan affekteer.

Moenie bestuur of masjinerie gebruik, tensy jy seker is dat jy nie geaffekteer is nie.

3. Hoe om RANCLAV 1 g te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem RANCLAV 1 g altyd presies soos wat jou dokter of apteker dit aan jou voorgeskryf het. Kontroleer met jou dokter of apteker as jy onseker is.

Die normale dosis is een RANCLAV 1 g tablet twee keer per dag geneem.

Sluk die tablet(te) heel in met ‘n glas water. Om die beste resultate te verkry, kan jy RANCLAV 1 g aan die begin van ‘n maaltyd neem.

Jou dosis kan verskillend wees in geval van wanneer jy nier- en/of lewerprobleme het.

Jou dokter sal jou inlig oor hoe lank jou behandeling met RANCLAV 1 g sal duur.

Neem jou medisyne soos voorgeskryf en vir so lank as wat dit voorgeskryf is. Moenie die behandeling vroeër staak nie, selfs as jy beter voel.

Lig jou dokter of apteker in as jy onder die indruk is dat die effek van RANCLAV 1 g te sterk of te swak is.

As jy vergeet het om RANCLAV 1 g te neem

As jy vergeet het om RANCLAV 1 g op die regte tyd te neem, neem dit so gou as wat jy onthou. As dit egter amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het en gaan terug na jou normale dosisskedule. Moenie ‘n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy oorgeslaan het nie.

As jy meer RANCLAV 1 g geneem het as wat jy behoort te neem:

Raadpleeg jou dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie inligtingstuk of sommige van die medisyne saam met jou sodat die dokter kan weet wat jy geneem het.

4. Moontlike newe-effekte

RANCLAV 1 g kan newe-effekte hê.

Nie alle newe-effekte wat vir RANCLAV 1 g aangemeld word, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl RANCLAV 1 g neem, moet jy asseblief jou gesondheidsorgvoorsiener raadpleeg vir advies.

As enige van die volgende gebeur, staak die gebruik van RANCLAV 1 g en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- Uitslae, galbulte, gejeuk, borskaskonstriksie, kortasemigheid of swelling van die gesig, lippe, mond of keel wat probleme om te sluk of asem te haal kan veroorsaak, enkels, hande /voete, floutes met spier- en gewrigspyne, en koors
- Ernstige velreaksies soos blase, sere of swere

Hierdie is baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige reaksie teenoor RANCLAV 1 g gehad het. Jy mag dringende mediese behandeling of hospitatlisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Ernstige diaree (wat bloed en slym bevat) saam met maagkrampe
- Konvulsies
- Vergeling van die vel en wit van die oë, sterk gekleurde urine of klei-kleurige stoelgange, met afname in

aptyt, abdominale pyn

- Ongewone bloeding of verhoogde bloedingsneiging, aanhoudende seerkeel en dikwelse infeksies, en/of anemie
- Verandering in normale urine produksie met troebel urine
- Veranderinge in geestesstatus (lomerigheid, verwarring)

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- Hoofpyn en duiseligheid
- Naarheid (voel mislik), braking (gooi op), slegte spysvertering, abnormale smaak, maagpyn, diaree, seer tong en mond, swart verkleuring van tong, verkleuring van tande, wit vlekke binne-in die mond of op die tong (mondsproei), veranderde smaak
- Vaginale afskeiding en gejeuk
- Moegheid, warmgloede
- Veluitslae, urtikarie en veelvuldige eriteem

Minder dikwelse newe-effekte:

- Verlenging van bloedingstyd en protrombientyd; bloedklonte
- Omkeerbare hiperaktiwiteit
- Dikwelse, intense drang om te urineer met lae rugpyn en/of koors & koue rillings (dit kan aandui dat jy kristalle in jou urine het)

Daar mag veranderinge in die resultate van sekere laboratoriumtoetse

- Abnormale lewerfunksietoetse
- Verhoogde aantal van ‘n tipe bloedsel wat eosinofiele genoem word
- Verhoogde aantal plaatjies

Lig asseblief jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte kry. Jy kan ook newe-effekte by SAHPRA

aanmeld *via* die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om inligting te verskaf oor die veiligheid van RANCLAV 1 g.

5. Hoe om RANCLAV 1 g te bewaar

- Bewaar alle medisyne buite die bereik van kinders.
- Bewaar by of benede 25 °C.
- Bewaar in die oorspronklike verpakking.
- Beskerm teen lig/vog.
- Moenie na die vervaldatum, soos op die etiket/karton aangedui, gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat RANCLAV 1 g bevat

Die aktiewe bestanddele is:

Amoksisillientrihidraat

gelykstaande aan amoksisillien 875 mg

Kaliumklavulanaat

gelykstaande aan klavulaansuur 125 mg.

Die ander bestanddele is: Basiese gebutileerde metakrilaat-ko-polimeer, kolloïdale silikondioksied, magnesiumstearaat, mikrokristallyne sellulose, Opadry wit (bedekkingsmiddel), povidoon, natriumstysel-glikolaat.

Hoe RANCLAV 1 g lyk en inhoud van die verpakking

Wit to naaswit, filmbedekte, kapsule-vormige tablette gedruk met 'RX509' op een kant en 'n keeplyn op die ander kant.

Karton bevat 10 tablette verpak in 'n PVC/PVdC-stulpverpakking binne-in 'n 4-lagige gelamineerde sakkie wat 'n droogmiddelsakkie bevat.

PVC/PVdC-stulpverpakking in 'n 4-lagige gelamineerde sakkie:

Helder PVC-film bedek met PVdC aan die binnekant met die bokant van harde getemperde, aluminiumfoelie bedek met hitteseëllak aan die binnekant.

Een stulpverpakking word binne-in ‘n 4-lagige gelamineerde sakkie geplaas wat ‘n droogmiddelsakkie bevat.

Die struktuur van die vier-lagige gelamineerde sakkie is as volg: Poliësterfilm/ Aluminiumfoelie/ Poliësterfilm / Poliëtileen.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14, Stormill Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingstuk was laas hersien in

Augustus 2022

Registrasienommer

A40/20.1.2/0568

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