APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

RANCLAV 625 Film Coated Tablets

Amoxicillin and potassium clavulanate

Sugar free

Read all of this leaflet carefully before you start taking RANCLAV 625

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other health care provider.
- **RANCLAV 625** 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 625** is and what it is used for
2. What you need to know before you take **RANCLAV 625**
3. How to take **RANCLAV 625**
4. Possible side effects
5. How to store **RANCLAV 625**
6. Contents of the pack and other information

1. What RANCLAV 625 is and what it is used for

RANCLAV 625 is an antibiotic and work by killing bacteria that cause infections. It contains two different medicines called amoxicillin and potassium clavulanate. Amoxicillin belongs to a group of medicines called 'penicillins". Amoxicillin can sometimes be stopped from working (made inactive) and the other component potassium clavulanate stops this from happening.

RANCLAV 625 is used to treat following bacterial infections:

- Sinus infections
- Middle ear infections
- Tonsil infection
- Chest infections with fever, chills, shortness of breath and a cough which produces yellow-green phlegm and occasionally blood (bronchitis and bronchopneumonia)
- Skin and soft tissue infections
- Infections of genital organs and urinary tract such as infection of bladder (cystitis), infection of urethra (urethritis), kidney infections (pyelonephritis)

RANCLAV 625 is only available with a doctor's prescription.

2. What you need to know before you take RANCLAV 625

Do not take RANCLAV 625 if:

- you are hypersensitive (allergic) to amoxicillin, potassium clavulanate, penicillin group of antibiotics, cephalosporin group of antibiotics (or any of the other ingredients of **RANCLAV 625** (listed in section 6) (an allergic reaction may include rash, itching, swelling of face, lips, or hands/feet or breathing difficulties).
- you have ever had liver problems or jaundice (yellowing of the skin and/or eyes) when taking amoxicillin and potassium clavulanate tablets.

Warnings and precautions

Take special care with **RANCLAV 625** if:

- you have ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- you have glandular fever [a viral infection which causes a sore throat, high temperature, tiredness, muscle pains and headache (infectious mononucleosis)]
- you have liver, kidney problems
- you are an elderly
- you have clotting problems
- you are suffering from a sexually transmitted disease (syphilis)
- you are suffering from a type of blood cell cancer (lymphatic leukaemia)
- you develop fits (convulsions) while you are taking **RANCLAV 625**
- you develop fever, rashes, swelling or have difficulty in breathing (acute generalized exanthemous pustulosis; hypersensitivity reaction).
- you develop loose stools while you are taking **RANCLAV 625** or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus along with fever and presence or absence of abdominal cramps (pseudomembranous enterocolitis), stop taking **RANCLAV 625** immediately, as this can be life threatening and contact your doctor. Do not take any anti-peristaltic medication (medicines increasing wave-like movement of the muscles in the walls of the digestive tract causing food and waste products to move through the body) to stop the diarrhoea while you are taking **RANCLAV 625.** You develop certain other fungal or bacterial infections while you are taking amoxicillin and potassium clavulanate tablets.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time including assessment of functioning of blood cell forming

organs, kidney and liver function to make sure the medicine is working and to prevent unwanted side effects.

Other medicines and RANCLAV 625

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

Some medicines and **RANCLAV 625** may interfere with each other. These include:

- Allopurinol (used for gout). If you are taking it may be more likely that you'll have an allergic skin reaction.
- Probenecid (used for gout). If you are taking it your doctor may decide to adjust your dose of **RANCLAV 625**.
- Warfarin, acenocoumarol (medicines to help stop blood clots). If taken with **RANCLAV 625** then extra blood tests may be needed.
- Hormonal oral contraceptives (birth controlling pills)
- Methotrexate (used to treat cancer or rheumatic diseases)
- Tetracyclines and other bacteriostatic medicines (medicines used to treat bacterial infections)
- Mycophenolate mofetil (used to prevent the rejection of transplanted organs)

These medicines may be affected by **RANCLAV 625**, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **RANCLAV 625**.

If you need a laboratory investigation such as blood test (red blood cell status tests or liver function tests) or urine test (for glucose), or other tests do inform your doctor about the

medicine you are taking. This is because amoxicillin and potassium clavulanate tablets can affect the results of these types of tests.

RANCLAV 625 with food and drink

RANCLAV 625 should be taken immediately before a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, 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 **RANCLAV 625** for use during pregnancy has not been established. Talk to your doctor if you are pregnant, you think you might be pregnant or planning to become pregnant, or are currently breastfeeding your baby. This medicine may cause unwanted side effects in new born through breast milk.

Driving and using machines

RANCLAV 625 may cause light-headedness, fits or allergic reactions. Make sure you know how you react to **RANCLAV 625** before you drive, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

3. How to take RANCLAV 625

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

Always take **RANCLAV 625** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water immediately before a meal.

It is important to drink lots of fluids while taking **RANCLAV 625** to help reduce the risk of forming amoxicillin crystals in urine.

Adults

The usual dose in adults is one tablet every 8 hours at the start of a meal.

Patients with kidney problems

If you have kidney problems or are undergoing haemodialysis, the dose and frequency will be decided by your doctor.

Your doctor may prescribe you a different dose and/or dose frequency depending on the type and severity of your infection. Similarly, the duration of treatment may also vary depending on the type and severity of your infection. Your doctor will tell you how long your treatment with **RANCLAV 625** will last.

If you have the impression that the effect of **RANCLAV 625** is too strong or too weak, tell your doctor or pharmacist.

If you take more RANCLAV 625 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You may have symptoms such as an upset stomach (feeling sick, being sick or diarrhoea), and symptoms of imbalance of water and minerals in body. In case you take more tablets than you should, take the medicine carton or this leaflet with you so your doctor will know what you have taken.

If you forget to take RANCLAV 625

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking RANCLAV 625

Do not stop taking **RANCLAV 625** without consulting your doctor.

Continue taking **RANCLAV 625** until the course is finished or for as long as your doctor tells you. Do not stop taking **RANCLAV 625** just because you feel better as the infection can return.

Do not stop taking, or change the dose without first checking with your doctor.

If you have any further questions on the use of **RANCLAV 625**, ask your doctor or pharmacist.

4. Possible side effects

RANCLAV 625 can have side effects.

Not all side effects reported for **RANCLAV 625** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **RANCLAV 625**, please consult your healthcare provider for advice.

If any of the following happens, stop taking RANCLAV 625 and tell your doctor immediately or go to the casualty department at your nearest hospital:

Frequent side effects:

- an allergic reaction characterised by rapid swelling of the face, tongue and windpipe which can cause great difficulty in breathing, shock, low blood pressure (angioedema)
- an allergic reaction characterised by symmetrical, red, raised skin areas all over the body (erythema multiforme)

Less frequent side effects:

- an allergic reaction characterised by widespread redness of the skin, severe peeling of the skin, or severe ulceration of the skin, eyes, mouth, nose and genitals (Stevens-Johnson syndrome)
- an allergic reaction characterised by detachment of the top layer of skin from all over the body, leaving large areas that look scalded. The loss of skin causes fluids and salts to ooze from the raw, damaged areas which can easily become infected (toxic epidermal necrolysis)
- widespread scaling of the skin, often with itching, skin redness, and hair loss (bullous exfoliative dermatitis)
- febrile drug eruption characterised by numerous small, primarily non-follicular, sterile pustules, arising within large areas of edematous erythema (acute generalized exanthemous pustulosis)

Side effects of unknown frequency:

- rash or hives, trouble in breathing, swelling of the face and throat. You may be having an allergic reaction which may need emergency treatment (anaphylactic reaction)
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results [including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)]
- yellowing of the skin and/or eyes (jaundice, cholestatic)

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **RANCLAV 625**. 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:

Less frequent side effects:

- Inflammation of blood vessels (hypersensitivity vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- Kidney disease, characterised by swelling in between the kidney tubules (interstitial nephritis)
- Fits (convulsions)

Side effects of unknown frequency:

- Fever, joint pain, swollen glands in the neck, armpit or groin (serum sickness like syndrome)
- Unusual bleeding or bruising under the skin symptoms includes purple or red-brown spots visible through the skin (thrombocytopenic purpura)
- Bleeding or bruising more easily than normal due to low blood platelet count, which can be reversible (thrombocytopenia, reversible)
- Illness resulting from the destruction of red blood cells symptoms include tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes (haemolytic anaemia)
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers due to lack of white blood cells, which is reversible (agranulocytosis, reversible)
- Liver disease symptoms includes nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis)
- Inflammation of the large intestine which causes watery diarrhoea usually with blood and mucus; stomach pain and/or fever (enterocolitis, antibiotic associated colitis including pseudomembranous colitis and haemorrhagic colitis)
- Inflammation of the protective membrane surrounding the brain symptoms includes fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light (aseptic meningitis)

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:

- Loose stools (diarrhoea)
- Feeling sick
- Vomiting
- Indigestion, pain in stomach, abnormal taste
- Rashes, hives, itching
- Dizziness, headache, tiredness and hot flushes
- Inflammation in vagina, fungal infection of genitals, increased infection due to other organisms

Less frequent side effects:

- Unusually active, which is reversible (hyperactivity, reversible)

Side effects of unknown frequency:

- Yeast infection of the mouth or skin folds (mucocutaneous candidiasis)
- Black tongue which looks hairy
- Inflammation of the stomach symptoms includes pain, nausea, vomiting, vomiting blood, blood in the bowel motions (gastritis)
- Mouth ulcers and cold sores (stomatitis)
- Swollen, red, sore tongue (glossitis)
- Discolouration of teeth (brown, yellow or gray staining)
- A condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal due to decreased number of red blood cells, symptoms includes tiredness, headaches, being short of breath when exercising, dizziness and looking pale (anaemia)

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 625**.

5. How to store RANCLAV 625

- Store all medicines out of reach of children.
- Store at or below 25 °C in the original package, protected from light and moisture.
- Do not remove the blisters from the carton until required for use.
- Do not take **RANCLAV 625** after the expiry date stated on the blister strips and carton.
- Return all unused or expired medicines to your pharmacist for safe disposal.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RANCLAV 625 contains

The active substance is amoxicillin and potassium clavulanate.

Each **RANCLAV 625** film-coated tablet contains

Amoxicillin trihydrate equivalent to amoxicillin 500 mg

Potassium clavulanate equivalent to clavulanic acid 125 mg

The other ingredients are: colloidal anhydrous silica, Eudragit E 100, isopropyl alcohol, magnesium stearate, methylene chloride, microcrystalline cellulose, Opadry 03B58965 white, PEG 400, povidone (K30), sodium starch glycolate.

What RANCLAV 625 looks like and contents of the pack

White to off-white film coated oval shaped tablets debossed with “RX713” on one side and plain on the other side.

PVC/PVdC blister of 10, 15 tablets in a laminated pouch along with 1 g sachet containing molecular sieve.

Holder of Certificate of Registration

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Access to the corresponding professional information

PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

RANCLAV 625 (Film Coated Tablets)

Amoksisillien en kaliumklavulanaat

Suikervry

Lees hierdie hele blad noukeurig deur voordat u begin om RANCLAV 625 te gebruik.

• Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.

• As u nog vrae het, moet u asseblief vir u dokter, apteker of ander gesondheidsorgverskaffer vra.

• **RANCLAV 625** is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is

1. Wat **RANCLAV 625** is en waarvoor dit gebruik word

2. Wat u moet weet voordat u **RANCLAV 625** drink

3. Hoe om **RANCLAV 625** te drink

4. Moontlike newe-effekte

5. Hoe om **RANCLAV 625** te bêre

6. Inhoud van die pak en ander inligting

1. Wat RANCLAV 625 is en waarvoor dit gebruik word

RANCLAV 625 is 'n antibiotikum en werk deur bakterieë wat infeksies veroorsaak dood te maak. Dit bevat twee verskillende middels genaamd amoksisillien en kaliumklavulanaat. Dit behoort aan 'n groep medisyne wat penisilliene genoem word. Amoksisillien kan soms ophou werk (onaktief gemaak word) en die ander komponent kaliumklavulanaat keer dat dit gebeur.

RANCLAV 625 word gebruik om die volgende bakteriële infeksies te behandel:

• Sinusinfeksies

• Middeloorinfeksies

• Mangelinfeksies

• Borsinfeksies met koors, kouekoors, kortasemheid en hoes wat geelgroen slym en af en toe bloed voortbring (brongitis en brongopneumonie)

• Infeksies van die vel en sagte weefsel.

• Infeksies in geslagsorgane en urienweë soos blaasinfeksie (sistitis), infeksie van die uretra (uretritis), nierinfeksies (piëlonefritis)

RANCLAV 625 is slegs op voorskrif van u dokter bekombaar.

2. Wat u moet weet voordat u RANCLAV 625 drink

Moenie RANCLAV 625 drink nie as:

• u is oorgevoelig (allergies) vir amoksisillien, kaliumklavulanaat, penisilliengroep-antibiotika, kefalosporiengroep-antibiotika (of enige van die ander bestanddele van **RANCLAV 625** is (gelys in afdeling 6) ('n allergiese reaksie kan uitslag, jeuk, swelling in die gesig, lippe of hande/voete of asemhalingsprobleme wees).

• u ooit lewerprobleme of geelsug (geel verkleuring van die vel) met die gebruik van antibiotika gehad het.

Waarskuwings en voorsorgmaatreëls

Wees besonder versigtig met **RANCLAV 625** as:

• u al ooit 'n allergiese reaksie (soos 'n uitslag) op antibiotika of ander stowwe gehad het.

• u klierkoors het ['n virale infeksie wat 'n seer keel, hoë temperatuur, moegheid, spierpyn en hoofpyn (aansteeklike mononukleose) veroorsaak]

• u lewer- of nierprobleme het

• u bejaard is

• u lewerprobleme het

• u aan 'n seksueel oordraagbare siekte (sifilis) ly

• u aan 'n tipe bloedkanker (limfatiese leukemie) ly

• u krampe tydens die gebruik van **RANCLAV 625** kry

• u koors, uitslag, swelling of asemhalingsprobleme kry (akute algemene eksanteme pustulose; hipersensitiwiteitsreaksie)

• u los stoelgang ontwikkel terwyl u **RANCLAV 625** gebruik of selfs 'n paar weke nadat u opgehou het om dit te drink. As dit ernstig of aanhoudend word, of as u agterkom dat u stoelgang bloed of slym bevat, saam met koors en die aan- of afwesigheid van buikkrampe (pseudomembraanenterokolitis), moet u **RANCLAV 625** onmiddellik stop, want dit kan lewensgevaarlik wees en skakel u dokter. Moenie terwyl u **RANCLAV 625** gebruik anti-peristaltiese medisyne (medisyne wat die golfagtige beweging van die spiere in die spysverteringskanaal verhoog, wat veroorsaak dat voedsel en afvalstowwe deur die liggaam beweeg) gebruik om die diarree te stop nie. U ontwikkel sekere ander swam- of bakteriële infeksies terwyl u tablette met amoksisillien en kaliumklavulanaat drink.

Hou al u doktersafsprake sodat u vordering gevolg kan word. U dokter kan van tyd tot tyd 'n paar toetse doen, waaronder beoordeling van die werking van die organe wat bloedselle vorm en van nier- en lewerfunksie, om seker te maak dat die medisyne werk en om ongewenste newe-effekte te voorkom.

Ander medisyne en RANCLAV 625

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).

Sommige medisyne en **RANCLAV 625** kan met mekaar interageer. Dit is onder meer die volgende:

• Allopurinol ('n middel vir jig). As u dit gebruik, is dit meer waarskynlik dat u 'n allergiese velreaksie kan hê.

• Probenesied ('n middel vir jig). As u dit gebruik, kan u dokter besluit om u dosis van **RANCLAV 625** aan te pas.

• Warfarien, asenokumarol (medisyne om bloedklonte te stop). As u dit saam met **RANCLAV 625** drink, is bykomende bloedtoetse nodig.

• Hormonale orale voorbehoedmiddels (geboortebeperkende pille)

• Metotreksaat (gebruik vir die behandeling van kanker of rumatiese siektes)

• Tetrasikliene en ander bakteriostatiese medisyne (medisyne wat gebruik word om bakteriële infeksies te behandel)

• Mikofenolaatmofetiel (om verwerping van oorgeplante organe te voorkom)

Hierdie medisyne kan deur **RANCLAV 625** beïnvloed word, of kan die werking daarvan beïnvloed. U moet dalk 'n ander dosis van medisyne drink, of u moet ander medisyne gebruik.

U dokter en apteker het meer inligting oor medisyne wat tydens die gebruik van **RANCLAV 625** versigtig hanteer of vermy moet word.

As u 'n laboratoriumondersoek soos bloedtoetse (rooibloedseltoetse of lewerfunksietoetse) of 'n urientoets (vir glukose), of ander toetse, nodig het moet u u dokter inlig oor die medisyne wat u gebruik. Dit is omdat tablette met amoksisillien en kaliumklavulanaat die uitslae van hierdie tipes toetse kan beïnvloed.

RANCLAV 625 saam met kos en drank

RANCLAV 625 moet onmiddellik voor ete gedrink word.

Swangerskap, borsvoeding en vrugbaarheid

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u hierdie medisyne drink.

Die veiligheid van **RANCLAV 625** vir gebruik tydens swangerskap is nie bepaal nie. Praat met u dokter as u swanger is, dink dat u swanger kan wees of van plan is om swanger te raak, of as u u baba tans borsvoed. Hierdie medisyne kan ongewenste newe-effekte in pasgebore babas veroorsaak.

Motorbestuur en gebruik van masjinerie

RANCLAV 625 kan lighoofdigheid, toevalle of allergiese reaksies veroorsaak. Maak seker dat u weet

hoe u op **RANCLAV 625** reageer voordat u 'n voertuig bestuur, masjinerie gebruik of enigiets anders doen wat gevaarlik kan wees as u duiselig of lighoofdig is.

3. Hoe om RANCLAV 625 te drink

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Gebruik **RANCLAV 625** altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.

Sluk die tablette heel met 'n glas water net voor 'n maaltyd af.

Dit is belangrik om baie vloeistowwe te drink terwyl u **RANCLAV 625** gebruik om die risiko vir die vorming van amoksisillienkristalle in urien te verlaag.

Volwassenes

Die gewone orale dosis vir volwassenes is een tablet elke 8 uur net voor etes.

Pasiënte met nierprobleme

As u nierprobleme het of as u hemodialise ondergaan, sal u dokter die dosis en frekwensie bepaal.

U dokter kan 'n ander dosis en/of doseerfrekwensie vir u voorskryf, afhangende van die tipe en erns van u infeksie. Net so kan die duur van die behandeling ook afhang van die tipe en erns van u infeksie.

U dokter sal vir u sê hoe lank u behandeling met **RANCLAV 625** sal duur.

Sê vir u dokter of apteker as u die indruk het dat die effek van **RANCLAV 625** te sterk of te swak is.As u meer **RANCLAV 625** gedrink het as wat u moes

Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

U kan simptome soos 'n omgekrapte maag (voel naar, diarree) hê en simptome van wanbalans tussen water en minerale in u liggaam. As u meer tablette gedrink het as wat u moes, moet u medisyneboksie

of hierdie pamflet saam neem sodat u dokter kan weet wat u gedrink het.

As u vergeet om RANCLAV 625 te drink

As u vergeet het om 'n dosis te drink, drink dit sodra u onthou. As dit egter amper tyd vir u volgende dosis is, slaan die dosis wat gemis is oor en gaan soos gewoonweg aan.

Moenie 'n dubbele dosis drink om vir vergete individuele dosisse op te maak nie.

As u ophou om RANCLAV 625 te drink

Moenie ophou om **RANCLAV 625** te drink sonder om u dokter te raadpleeg nie.

Gaan voort met die gebruik van **RANCLAV 625** totdat die kursus voltooi is of vir so lank as wat u dokter vir u sê. Moenie net omdat u beter voel ophou om **RANCLAV 625** te drink nie omdat die infeksie kan terugkom.

Moenie ophou om dit te drink en moenie die dosis verander sonder om eers met u dokter te praat nie.

As u nog vrae oor die gebruik van **RANCLAV 625** het, vra vir u dokter of apteker.

4. Moontlike newe-effekte

RANCLAV 625 kan newe-effekte veroorsaak.

Nie al die newe-effekte wat vir **RANCLAV 625** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u **RANCLAV 625** drink, moet u u gesondheidsorgverskaffer om advies raadpleeg.

As enige van die volgende voorkom, moet u ophou om RANCLAV 625 te drink en dadelik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

Algemene newe-effekte:

• 'n allergiese reaksie gekenmerk deur vinnige swelling van die gesig, tong en lugpyp wat asemhalingsprobleme, skok, lae bloeddruk kan veroorsaak (angio-edeem)

• 'n allergiese reaksie wat gekenmerk word deur simmetriese, rooi, opgehewe velareas oor die hele liggaam (multivorme eriteem)

Newe-effekte wat minder dikwels voorkom:

• 'n allergiese reaksie wat gekenmerk word deur wydverspreide rooiheid van die vel, erge afskilfering van die vel of erge ulserasie van die vel, oë, mond, neus en geslagsdele (Stevens-Johnsonsindroom)

• 'n allergiese reaksie gekenmerk deur die losgaan van die boonste vellaag regoor die liggaam, wat groot dele laat wat lyk asof dit gebrand het. Die verlies aan vel veroorsaak dat vloeistowwe en soute uit die rou, beskadigde gebiede sypel wat maklik besmet kan raak (toksiese epidermale nekrolise)

• wydverspreide afskilfering van die vel, dikwels met jeuk, rooi vel en haarverlies (blaasagtige eksfoliatiewe dermatitis)

• koorsige geneesmiddeluitbarsting wat gekenmerk word deur talle klein, hoofsaaklik niefollikulêre, steriele pustules, wat in groot gebiede van edeem-eriteem ontstaan (akute algemene eksanteme pustulose)

Newe-effekte met onbekende frekwensie:

• uitslag of galbulte, asemhalingsprobleme, swelling in die gesig en keel. U het moontlik 'n allergiese reaksie waarvoor noodbehandeling nodig is (anafilaktiese reaksie)

• griepagtige simptome met uitslag, koors, geswelde kliere en abnormale bloedtoetsuitslae [waaronder meer witbloedselle (eosinofilie) en lewerensieme - geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS)]

• geel verkleuring van die vel en/of oë (geelsug, cholestaties)

Hierdie is baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op **RANCLAV 625** het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

Minder algemene newe-effekte:

• inflammasie van die bloedvate (hipersensitiewe vaskulitis) wat as rooi of pers opgehewe kolle op die vel sigbaar kan wees, maar ander dele van die liggaam kan aantas

• Niersiekte, gekenmerk deur swelling tussen die nierbuisies (interstisiële nefritis)

• Toevalle (stuiptrekkings)

Newe-effekte met onbekende frekwensie:

• Koors, gewrigspyn, geswelde kliere in die nek, oksels of lieste (sindrome soos serumsiekte)

• Ongewone bloeding of kneusplekke onder die vel met simptome soos pers of rooi-bruin kolle wat deur die vel sigbaar is (trombositopeniese purpura).

• Bloei of kneus makliker as normaal weens lae bloedplaatjie-telling, wat omkeerbaar kan wees (trombositopenie, omkeerbaar)

• 'n Siekte wat ontstaan vanweë die vernietiging van rooibloedselle met simptome soos moegheid, hoofpyn, kortasemheid tydens oefening, duiseligheid, bleekheid en geel verkleuring van die vel en/of oë (hemolitiese anemie)

• Aanhoudende infeksies soos koors, erge kouekoors, seer keel of maagsere as gevolg van gebrek aan witbloedselle, wat omkeerbaar is (agranulositose, omkeerbaar)

• Lewersiekte met simptome soos naarheid, braking, aptytverlies, algemene ongesteldheid, koors, jeuk, geel verkleuring van die vel en oë, ligkleurige feses donkergekleurde urien (hepatitis)

• Ontsteking van die dikderm wat waterige diarree veroorsaak, gewoonlik met bloed en slym; maagpyn en/of koors (enterokolitis, kolitis vanweë antibiotika, waaronder pseudomembraankolitis en hemorragiese kolitis)

• Inflammasie van die beskermende membraan rondom die brein met simptome soos koors, naarheid, braking, hoofpyn, stywe nek en uiterste sensitiwiteit vir helder lig (aseptiese meningitis)

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Algemene newe-effekte:

• Los stoelgange (diarree)

• Naarheid

• Braking

• Slegte spysvertering, maagpyn, abnormale smaak

• Veluitslag, galbulte, jeuk

• Duiseligheid, hoofpyn, moegheid en warm gloede

• Ontsteking in die vagina, swaminfeksie op geslagsdele, eer infeksies as gevolg van ander organismes

Newe-effekte wat minder dikwels voorkom:

• Ongewoon aktief, wat omkeerbaar is (hiperaktiwiteit, omkeerbaar)

Newe-effekte met onbekende frekwensie:

• Gisinfeksie in die mond of velvoue (mukokutane kandidiase)

• Swart tong wat harig lyk

• Ontsteking van die maag met simptome soos pyn, naarheid, braking, braak van bloed, bloed in die stoelgang (gastritis)

• Mondsere en koorsblare (stomatitis)

• Geswelde, rooi, seer tong (glossitis)

• Verkleuring van die tande (bruin, geel of grys vlekke)

• 'n Toestand waarin die hoeveelheid suurstofdraende pigment (hemoglobien) in die bloed onder normaal is as gevolg van minder rooibloedselle, met simptome soos moegheid, hoofpyn, kortasemheid tydens oefening, duiseligheid en bleekheid (bloedarmoede)

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief daarvan sê.

Aanmeld van newe-effekte

Praat met u dokter of apteker as u newe-effekte ervaar. Dit sluit alle moontlike newe-effekte in wat nie in hierdie blad gelys word nie. U kan newe-effekte ook by SAROGP (SAHPRA) aanmeld *via* die vorm vir die aanmeld van nadelige geneesmiddelreaksies, naamlik "**6.04 Adverse Drug Reaction Reporting Form**" wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **RANCLAV 625** te gee.

5. Hoe om RANCLAV 625 te bêre

• Hou alle medisyne buite bereik van kinders.

• Bêre by of onder 25 °C in die oorspronklike houer en beskerm teen lig.

• Hou die stulppakke in die kartonne totdat dit benodig word.

• Moenie **RANCLAV 625** na die vervaldatum op die stulpstrook en karton drink nie.

• Gee alle ongebruikte of vervalde medisyne vir veilige wegdoening terug aan u apteker.

• Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting

Wat RANCLAV 625 bevat

Die aktiewe stowwe is amoksisillientrihidraat en kaliumklavulanaat.

Elke **RANCLAV 625**-filmbedekte tablet bevat:

Amoksisillientrihidraat gelykstaande aan 500 mg amoksisillien

Kaliumklavulanaat gelykstaande aan 125 mg klavulaansuur

Die ander bestanddele is kolloïdale watervrye silika, Eudragit E 100, isopropielalkohol, magnesiumstearaat, metileenchloried, mikrokristallyne sellulose, wit Opadry 03B58965, PEG 400, povidoon (K30), natriumstyselglikolaat.

Hoe RANCLAV 625 lyk en die inhoud van die pakkie

Wit tot naaswit ovaalvormige tablet, met “RX713“ op die een kant gedruk en die ander kant glad. PVC/PVdC-stulpstrook met 10 of 15 tablette in 'n gelamineerde sakkie saam met 'n sakkie wat 1 g molekulêre siwwe bevat.

Houer van die registrasiesertifikaat

Ranbaxy Pharmaceuticals (Edms) Bpk

Lautreweg 14, Stormill, Uitbr. 1

Roodepoort, 1724, Suid-Afrika

Hierdie blad is laas hersien op

25 Mei 2021

Registrasienommer

50/20.1.2/0227