Front Top

435 mm

380 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

QUESARA 25 mg (Film-coated Tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 5,175 mg)

QUESARA 100 mg (Film-coated Tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 20,70 mg)

QUESARA 200 mg (Film-coated Tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 41,40 mg

QUESARA 300 mg (Film-coated Tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 62,10 mg)

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

1. What QUESARA is and what it is used for

QUESARA belongs to a group of medicines called antipsychotics.
QUESARA is used to treat schizophrenia with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.
QUESARA is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with mood swings.

2. What you need to know before you take QUESARA

Do not take QUESARA:
- **if you are allergic to quetiapine or any of the ingredients of QUESARA.**
- **if you are pregnant or breastfeeding.**
- **if you have advanced liver or kidney diseases.**
- **if you are taking the following medicines:**
  - **amprenavir, indinavir, nelfinavir, ritonavir and saquinavir (for HIV treatment).**
  - **fluconazole, ketoconazole (antifungal medicines).**
  - **erythromycin, clarithromycin (for infections) and nefazadone (for depression)**

Warnings and precautions
Take special care with QUESARA:
Tell your doctor or healthcare professional before you take QUESARA:
- **about any past or present medical problems**
- **about any allergies you have or have had**
- **if you are pregnant or breastfeeding your child**
- **if you have kidney or liver disease**
- **if you suffer from any blood disorder**
- **if you have had a stroke recently**
- **if you have diabetes**
- **if you have low or high blood pressure, a family history of heart disease, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart, or if you are taking any medicines that may have an impact on the way your heart beats.**
- **if you have epilepsy**
- **if you are elderly and suffer from dementia (mental illness) characterised by a decline in memory, language, problem-solving and other thinking skills that affect a person's ability to perform everyday activities.**
- **if you have an enlarged prostate, have bowel obstruction or eye problems (increased pressure in the eyes or glaucoma)**
- **if you have a history of alcohol or drug abuse.**

QUESARA should not be given to children or adolescents
While taking QUESARA:
- **Thoughts of suicide and worsening of your depression:**
  If you are depressed, you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since QUESARA takes time to work, usually about two weeks but sometimes longer. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.
- **If you observe sudden infections, inform your doctor. The can happen because of decreased white blood cell count in your blood, which leads to decreased immunity.**
- **QUESARA can cause high blood sugar levels and in some cases could result in coma or death. Tell your doctor if you observe symptoms like excessive thirst, eating and urination. Your doctor will monitor your blood sugar levels on a regular basis and treat you for the high blood sugar.**
- **High levels of fat (triglycerides and cholesterol) in the blood have been seen in patients taking QUESARA. Your doctor will do blood tests to check certain fat levels before you start taking QUESARA and regularly during treatment.**
- **Weight gain has been seen in patients taking QUESARA. You and your doctor should check your weight regularly.**
- **QUESARA may cause inflammation of the pancreas (pancreatitis). Inform your doctor if you feel symptoms like indigestion, nausea, vomiting and loss of appetite.**
- **Tell your doctor if you experience lightheadedness or fainting caused by a sudden change in heart rate and blood pressure when standing up too quickly from a sitting or lying position.**
- **QUESARA may cause sleep apnoea which is a potentially serious sleep disorder in which breathing repeatedly stops and starts. Inform your doctor if you suffer from sleep disorders.**
- **QUESARA may cause difficulty on swallowing and a condition in which food, liquids, saliva or vomit is breathed into the airways. Inform your doctor if you experience coughing, difficulty breathing and in some cases choking.**
- **QUESARA can cause abdominal pain followed by difficulty in passing stools (constipation). Inform your doctor if you experience these symptoms.**
- **Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given QUESARA, tell your doctor.**
- **QUESARA may cause severe restlessness, with the need to move often accompanied by an inability to sit or stand still especially during the first few weeks of treatment. Inform your doctor if you experience these symptoms.**
- **Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor.**
- **You may experience sleepiness, nausea, vomiting, headache, diarrhoea if you suddenly stopping treatment with QUESARA. Your doctor will gradually reduce your dose over one or two weeks to prevent withdrawal symptoms.**
- **QUESARA may cause an increase in prolactin levels characterised with irregular or absent menstrual periods, infertility, menopausal symptoms (hot flashes and vaginal dryness), and after several years, osteoporosis (thinning and weakening of the bones). High prolactin levels can also cause milk discharge from the breasts.**

Other medicines and QUESARA
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
You might feel drowsy if QUESARA is taken in combination with alcohol, antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).
Inform your doctor if you are taking the following medicines:
- **Ketoconazole, fluconazole or itraconazole (for fungal infections)**
- **Phenytoin, sodium valproate or carbamazepine (for epilepsy)**
- **Levodopa (for Parkinson's disease)**
- **Imipramine and fluoxetine**
- **Cimetidine**
- **Lithium (other anti-psychotic medicines).**
- **Risperidone, haloperidol and thioridazine (anti-psychotic medicines).**
- **Medicines that have an impact on the way your heart beats, for example, medicines that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (to treat infections).**
- **Medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.**
- **If you are having a urine screen, taking QUESARA may cause positive results for methadone or certain medicines for depression called tricyclic antidepressants when some test methods are used, even though you may not be taking methadone or tricyclic antidepressants. Confirmation of the results by more specific tests is recommended.**

QUESARA with food and drink and alcohol
QUESARA can be taken with or without food. Do not drink any alcohol while taking QUESARA as the alcohol together with QUESARA will make you drowsy.
Grapefruit juice should be avoided.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking QUESARA.

You should not take QUESARA during pregnancy.
QUESARA should not be taken if you are breastfeeding.

The following symptoms which can represent withdrawal may occur in newborn babies of mothers that have used QUESARA in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines
Sleepiness, decreased alertness, dizziness and drowsiness have been reported in patients receiving QUESARA. If you experience these you should evaluate your ability to drive or to operate machinery.

QUESARA contains
QUESARA contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take QUESARA.
QUESARA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take or give QUESARA

- **Do not share medicines prescribed for you or your child with any other person.**
- **Always take or give QUESARA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.**
- **Your doctor will tell you exactly how much medicine to take or give and when to take or give it.**

The usual dose is
QUESARA is taken once or twice daily. Your doctor may adjust your daily dose between 150 to 800 mg a day depending on your individual treatment and needs.
Consult your doctor if your symptoms return but do not stop taking QUESARA unless your doctor tells you to.
Take the tablets with a sufficient quantity of liquid (e.g. one glass of water). Do not chew the tablets.
Your doctor will tell you how long your treatment with QUESARA will last. Do not stop treatment early. If you have the impression that the effect of QUESARA is too strong or too weak, tell your doctor or pharmacist.
Do not take or give more QUESARA 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.
Overdosage may cause decreased blood pressure, confusion, problems in urination, depression, difficulty in breathing, sleepiness and coma.

If you forget to take or give QUESARA
It is important to take your QUESARA regularly at the same time each day. If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking or giving QUESARA
Take QUESARA for as long as your doctor recommends. Do not stop taking QUESARA unless your doctor tells you to.
If you suddenly stop taking QUESARA, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea, headache, diarrhoea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment.

4. Possible side effects

QUESARA can have side effects.
Not all side effects reported for QUESARA are included in the leaflet. Should your general health worsen or if you experience any untoward effects while taking QUESARA, please consult your healthcare provider for advice.
If any of the following happens, stop taking or giving QUESARA and tell your doctor immediately or go to the casualty department at your nearest hospital.
- **Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.**
- **A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.**
- **Difficulty swallowing.**
- **Very marked drowsiness.**
- **A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called "neuroleptic malignant syndrome").**
- **Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.**
- **Fits (seizures).**

These are all very serious side effects. If you have them, you may have had a serious reaction to QUESARA. You may need urgent medical attention or hospitalization.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- **Priapism (long-lasting and painful erection).**
- **Difficulty in passing urine.**
- **Uncontrollable movements, mainly of your face or tongue**
- **Yellowing of the skin and eyes (jaundice).**
- **Severe rash, blisters, or red patches on the skin.**
- **Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).**
- **A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).**

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

Contact your doctor immediately or go to the nearest hospital if any of the following events happens to you (these are also described below). These events are rare and are sometimes seen with medicines used to treat mental illness
- **Very marked drowsiness**
- **Fits (seizures).**
- **Priapism (long-lasting and painful erection).**

Tell your doctor if you notice any of the following:
Frequent side effects
- **Dizziness (may lead to falls).**
- **Headache.**
- **Feeling sleepy.**
- **Disturbance in speech and language.**
- **Abnormal muscle movements (These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.**
- **Dry mouth.**
- **Constipation.**
- **Upset stomach (indigestion).**
- **Vomiting.**
- **Discontinuation symptoms (symptoms which occur when you stop taking QUESARA) Include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.**
- **Feeling weak.**
- **Swelling of arms or legs.**
- **Feeling irritated.**
- **Fever.**
- **Putting on weight.**
- **Changes in the amount of certain fats (triglycerides and total cholesterol), increased levels of sugar in the blood.**
- **Feeling more hungry.**
- **Rapid heartbeat, feeling like your heart is pounding, racing or has skipped beats.**
- **Low blood pressure when standing up.**
- **Blurred vision.**
- **Abnormal dreams and nightmares, thoughts of suicide and worsening of your depression.**
- **Shortness of breath, stuffy nose, changes in the amount of thyroid hormones in your blood.**
- **Increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:**
  - **Men and women to have swelling breasts and unexpectedly produce breast milk.**
  - **Women to have no monthly periods or irregular periods.**
- **Decreases in the number of certain types of blood cells.**
- **Increases in the amount of liver enzymes measured in the blood.**

Less frequent side effects
- **Fits or seizures.**
- **Unpleasant sensations in the legs (also called restless legs syndrome).**
- **Uncontrollable movements, mainly of your face or tongue.**
- **Fainting (may lead to falls).**
- **Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.**
- **Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.**
- **A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.**
- **Difficulty swallowing.**
- **Inflammation of the pancreas.**
- **Bowel obstruction.**
- **Sexual dysfunction.**
- **Along-lasting and painful erection (priapism).**
- **Swelling of breasts and unexpected production of breast milk (galactorrhoea).**
- **Menstrual disorder.**
- **Diabetes.**
- **Worsening of pre-existing diabetes.**
- **Decrease in the amount of sodium in the blood.**
- **A condition (called "metabolic syndrome") where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in "good" cholesterol" (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar.**
- **Change in electrical activity of the heart seen on ECG (QT prolongation), a slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.**
- **Difficulty in passing urine.**
- **Decrease in the amount of red blood cells.**
- **A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called "neuroleptic malignant syndrome").**
- **Body temperature decreased (hypothermia).**
- **Yellowing of the skin and eyes (jaundice).**
- **Inflammation of the liver (hepatitis).**
- **Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.**
- **Walking, talking, eating or other activities while you are asleep.**
- **Increased blood creatine phosphokinase (a substance from the muscles).**
- **Severe rash, blisters, or red patches on the skin.**
- **Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).**
- **A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).**
- **Inappropriate secretion of a hormone that controls urine volume.**
- **Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).**

Side effects with unknown frequency
- **Skin rash with irregular red spots (erythema multiforme).**
- **Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).**
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which consists of flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes).**
- **Symptoms of withdrawal may occur in newborn babies of mothers that have used QUESARA during their pregnancy.**
- **Stroke.**

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

Reporting of side effects
If you or your child get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "8.04 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 QUESARA.

5. How to store QUESARA

Store all medicines out of reach of children.
Store at or below 25°C.
Keep the blister in the carton until required for use.
Keep the HDPE container tightly closed.
Store in the original package in order to protect from light and moisture.
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What QUESARA contains
QUESARA 25 mg:
The active substance is 25 mg quetiapine (as quetiapine fumarate).
QUESARA 100 mg:
The active substance is 100 mg quetiapine (as quetiapine fumarate).
QUESARA 200 mg:
The active substance is 200 mg quetiapine (as quetiapine fumarate).
QUESARA 300 mg:
The active substance is 300 mg quetiapine (as quetiapine fumarate).

The other ingredients are microcrystalline cellulose, dibasic calcium phosphate, sodium starch glycolate, lactose monohydrate, povidone, colloidal silicon dioxide, magnesium stearate. The tablets are coated with coating made up of hypromellose, titanium dioxide (Colour Index No.: 77891), and polyethylene glycol 400.
In addition QUESARA 25 mg contains iron oxide yellow (Colour Index No.: 77492), iron oxide red (Colour Index No. 77491) and QUESARA 100 mg contains, iron oxide yellow (Colour Index No. 77492).
QUESARA 25 mg contains sugar (5,175 mg lactose monohydrate).
QUESARA 100 mg contains sugar (20,70 mg lactose monohydrate).
QUESARA 200 mg contains sugar (41,40 mg lactose monohydrate).
QUESARA 300 mg contains sugar (62,10 mg lactose monohydrate).

What QUESARA looks like and contents of the pack
QUESARA 25 mg
Peach coloured, round, film-coated tablets debossed with "F 71" on one side and plain on the other side.
QUESARA 100 mg
Yellow coloured, round, film-coated tablets debossed with "F 73" on one side and plain on the other side.
QUESARA 200 mg
White coloured, round, film-coated tablets debossed with "F 75" on one side and plain on the other side.
QUESARA 300 mg
White coloured, capsule shaped, film-coated tablets debossed with "F 75" on one side and plain on the other side.

QUESARA 25 mg:
1) Blister Pack:
Tablets are packed in white opaque PVC/PVdC 250/60 PVC film coated with 60 gsm PVdC as the forming material and plain 25 micron, aluminium foil, 6-8 gsm HSL, as the lidding material. Each blister contains 10 tablets.
Pack size: 100's – Each carton contains 10 blisters of 10 tablets each.
2) HDPE Container Pack:
Tablets are packed in white round 60 ml HDPE bottle with 33 neck finish closed with 33 mm child resistant closure with pulp and heat seal. Each container contains 100 tablets.
Pack size: 100's - One HDPE container contains 100 tablets.

QUESARA 100 mg:
1) Blister Pack:
Tablets are packed in white opaque PVC/PVdC 250/60 PVC film coated with 60 gsm PVdC as the forming material and plain 25 micron, aluminium foil, 6-8 gsm HSL, as the lidding material. Each blister contains 10 tablets.
Pack size: 100's – Each carton contains 10 blisters of 10 tablets each.
90's – Each carton contains 9 blisters of 10 tablets each.
2) HDPE Container Pack:
Tablets are packed in white round 60 ml HDPE bottle with 33 neck finish closed with 33 mm child resistant closure with pulp and heat seal. Each container contains 100 tablets.
Pack size: 100's - One HDPE container contains 100 tablets.

QUESARA 200 mg:
1) Blister Pack:
Tablets are packed in white opaque PVC/PVdC 250/60 PVC film coated with 60 gsm PVdC as the forming material and plain 25 micron, aluminium foil, 6-8 gsm HSL, as the lidding material. Each blister contains 10 tablets.
Pack size: 100's – Each carton contains 10 blisters of 10 tablets each.
60's – Each carton contains 6 blisters of 10 tablets each.
2) HDPE Container Pack:
Tablets are packed in white round 100 ml HDPE bottle with 38-400 neck finish closed with 38 mm child resistant closure with pulp and heat seal. Each container contains 100 tablets.
Pack size: 100's - One HDPE container contains 100 tablets.

QUESARA 300 mg:
1) Blister Pack:
Tablets are packed in white opaque PVC/PVdC 250/60 PVC film coated with 60 gsm PVdC as the forming material and plain 25 micron, aluminium foil, 6-8 gsm HSL, as the lidding material. Each blister contains 10 tablets.
Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.
60's – Each carton contains 6 blisters of 10 tablets each.
2) HDPE Container Pack:
Tablets are packed in white round 75 ml HDPE bottle with 38-400 neck finish closed with 38 mm child resistant closure with pulp and heat seal. Each container contains 60 tablets.
Pack size: 60's - One HDPE container contains 60 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
09 February 2021

Registration number
QUESARA 25 mg: 47/2.6.5/0144
QUESARA 100 mg: 47/2.6.5/0145
QUESARA 200 mg: 47/2.6.5/0146
QUESARA 300 mg: 47/2.6.5/0147

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodsespprodute.co.za/ or contact 011 852 1169

QUESARA
Quetiapine Tablets
PM0362502

Back Top

435 mm

380 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

QUESARA 25 mg (Filmbedekte Tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 5,175 mg)

QUESARA 100 mg (Filmbedekte Tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 20,70 mg)

QUESARA 200 mg (Filmbedekte Tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 41,40 mg)

QUESARA 300 mg (Filmbedekte Tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 62,10 mg)

Lees hierdie hele inligtingsblad aandagtig deur, voordat jy QUESARA gebruik
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of apteker.
- QUESARA is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander mense te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

Wat in hierdie inligtingsblad is

1. Wat QUESARA is en waarvoor dit gebruik word,
2. Wat jy behoort te weet voordat jy QUESARA gebruik.
3. Hoe om QUESARA te gebruik
4. Moontlike newe-effekte
5. Hoe om QUESARA te berg
6. Inhoud van die pak en ander inligting

1. Wat QUESARA is en waarvoor dit gebruik word

QUESARA behoort aan 'n groep medisyne wat antipsigotiese middels genoem word:.
QUESARA word gebruik om aksiefsimptome te behandel met simptome soos om dinge wat nie bestaan nie te hoor, te sien, of aan te voel, verkeerde oortuigings, ongewone sigtenog, en teruggetrokkenheid. Mense met hierdie siekte kan ook depressief, angstig of gespanne voel.
QUESARA is ook 'n gemoedstabiliseerder wat verdere gebeure van die uitbarstende fase en lae (depressiewe) uitersies van bulle, geassosieer met buierigheid, voorkom.

2. Wat jy behoort te weet voordat jy QUESARA neem

Moet nie QUESARA neem nie:
- indien jy **allergies** is vir kwetiapien of enige van die ander bestanddele van QUESARA.
- indien jy swanger is of borsvoed.
- indien jy 'n gevorderde lewer- of niersiekte het.
- indien jy die volgende mediseyne gebruik:
  - saquinavir, indinavir, nelfinavir, ritonavir en salkwinavir (vir MIV behandeling);
  - ketokonasool, ketokonasool (swambestrydende mediseyne),
  - eritromisien, klaritromisien (vir infeksies) en nefasadoon (vir depressie)

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met QUESARA:
Vertel jou dokter of gesondheidsorgverskaffer voordat jy QUESARA neem:
- oor enige mediese probleme in die verlede of tans,
- oor enige allergies wat jy het of gehad het.
- indien jy swanger is of jou kind borsvoed.
- as jy 'n lae-of lewersiekte het.
- indien jy aan enige bloedversteuring ly.
- as jy onlangs 'n beroerte gehad het.
- indien jy diabetes het.
- as jy lae of hoë bloeddruk het, 'n familie geskiedenis van hartsiekte, hyvoorbeeld probleme met hartritme, verswakking van die hartspier of ontsteking van die hart, of indien jy enige mediseyne neem wat moontlik 'n inwerking kan hê op die manier waarop jou hart klop.
- as jy jeukpasie het.
- as jy 'n bejaarde persoon is en jy aan demensie (geestesongesteldheid) gekarakteriseer deur 'n afname in geheue, spraak, probleemoplossing en ander denkvaardighede wat 'n persoon se vermoë om daagliikse take uit te voer, bemvloed.
- indien jy 'n vergrote prostaat het, 'n obstruksie in jou derms of oogprobleme (verhoogde druk in die oë of gloukoom).
- indien jy 'n geskiedenis van alkohol- of dwelmmisbruik het.

QUESARA moet nie aan kinders of adolessente gegee word nie.
Terwyl QUESARA geneem word:
- Gedagtes van selfmoord en verergering van jou depressie:
  Indien jy depressief is, kan jy soms daarraan dink om jouself leed aan te doen of om selfmoord te pleeg. Hierdie gedagtes kan toeneem wanneer daar met die behandeling begin word, aangesien QUESARA tyd neem om te begin werk, gewoonlik ongeveer twee weke maar soms langer. Indien jy op enige tydstip daaraan dink om jouself leed aan te doen, of om selfmoord te pleeg, moet jy jou dokter kontak of onmiddellik na 'n hospitaal gaan. Jy mag dit moontlik nuttig vind om 'n familielid of hegte vriend te vertel dat jy depressief is en hulle te vra om hierdie inligtingsblik te lees. Jy kan hulle moontlik vra om jou te vertel indien hulle dink dat jou depressie vererger, of as hulle bekommerd is oor veranderinge in jou gedrag.
- Indien jy siekte infeksies waarneem, moet jy jou dokter in kennis stel. Dit kan gebeur as gevolg van die verminderde aantal witbloedselle in jou bloed, wat lei tot verlaagde immuniteit.
- QUESARA kan hoë bloedsuikervlakke veroorsaak en in sommige gevalle tot 'n koma of die dood lei. Vertel jou dokter as jy simptome soos oormatige dors, eet en urinering ervaar. Jou dokter sal jou bloedsuikervlakke op 'n gereelde basis monitor en jou behandel vir die hoë bloedsuiker.
- Hoë vlakke van vet (triglisiriede en cholesterol) in die bloed is al gesien in pasiënte wat QUESARA gebruik. Jou dokter sal bloedtoetse doen om sekere veranderke te kontroleer voordat jy QUESARA begin neem en gereeld tydens die behandeling.
- Gewigstoename is gesien in pasiënte wat QUESARA gebruik. Jy en jou dokter moet jou gewig gereeld kontroleer.
- QUESARA kan ontsteking van die pankreas (pankreatitis) veroorsaak. Stel jou dokter in kennis indien jy simptome soos slegte spysvertering, naarheid, braking en verlies aan eetlus ervaar.
- Vertel jou dokter indien jy ligkoofdigheid of floutjies ervaar, veroorsaak deur 'n skielike verandering in hartiempo en bloeddruk, wanneer jy te vinnig vanuit 'n sit- of liposisie opstaan.
- QUESARA kan **sleepapnee** veroorsaak, wat 'n potensieel ernstige **sleepversteuring** is waarin asemhaling herhaaldelik ophou en begin. Lig jou dokter in indien jy aan sleapversteuring ly.
- QUESARA kan dit moeilik maak om te sluk an 'n toestand veroorsaak waarin voedsel, vloeistowwe, speeksel of braaksel in die lugweg ingaseem word. Stel jou dokter in kennis indien jy hoes, probleme met asemhaling en in kommige gevalle, verstikking ervaar.
- QUESARA kan buikpyn veroorsaak, gevolg deur probleme met stoelgange (hardlywigheid). Stel jou dokter in kennis as jy hierdie simptome ervaar.
- Hierdie tipe mediseyne kan ongewone bewegings van vorat die gesig of long veroorsaak. Vertel jou dokter indien dit gebeur nadat QUESARA aan jou gegee is.
- QUESARA kan erge naelsiekoshaid veroorsaak, met die behoefte daaraan om te beweeg, gewoonlik vergesel met die onvermoë om stil te sit of stil te staan, vertel gedurende die eerste paar weke van die behandeling. Vertel jou dokter indien jy hierdie simptome ervaar.
- Hierdie tipe mediseyne veroorsaak bee seide 'n kombinasie van koors, vinnige asemhaling, sweet, spierstyfheid en lomerigheid of slapenghaid. Wanneer dit gebeur, kontak jou dokter.
- As jy siekte die behandeling met QUESARA stop, kan jy moontlik slaperigheid, naarheid, braking, hoofpyn, diarree ervaar. Jou dokter sal jou dosis geleidelik oor een of twee weke verminder om ontrekkingsimptome te voorkom.
- QUESARA kan 'n toename in prolaktienvlakke veroorsaak wat gekenmerk word deur onreëlmatige of afwesige maandelondes, onvrugbaarheid, menopousale simptome (warm gloeie en vaginale droogheid), en na 'n paar jaar, osteoporose (verdunning en verswakking van die bene). Hoë prolaktienvlakke kan ook melkafskeiding uit die borste veroorsaak.

Andermediseyne en QUESARA
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander mediseyne neem. (Dit sluit alle komplementêre of tradisionele mediseyne in.)
Jy kan lomerig voel as QUESARA geneem word in kombinasie met alkohol, antidepressante of mediseyne wat geneem word vir angstigheid of om jou te help slaap (kalmeermiddels).
Sien jou dokter in kennis indien jy die volgende mediseyne neem:
- Ketokonasool, fluikonasool of itrakonasool (vir swambestamting)
- Fenitoïen, natriumvalproaat of karbamasepen (vir epilepsie)
- Levodopa (vir Parkinson se siekte)
- Imipramien en fluoksetien
- Simetidien
- Litium (ander antipsigotiese middels)
- Risperidoon, haloperidol en tioridasien (antipsigotiese middels)
- Mediseyne wat 'n inwerking het op die manier waarop jou hart klop, byvoorbeeld mediseyne wat 'n verbreking in elektrolitiese (soos kalium- of magnesiumvlakke) kan veroorsaak, soos diuretika (waterpille) of sekere antibiotika (om infeksies te behandel),
- Mediseyne (naamlik "antichollnergiese middels") wat die manier waarop senuweeselle funksioneer beinvloed, om sodoende sekere mediese toestande te behandel.
- Indien jy 'n uitenasting ondergaan, kan die neem van QUESARA moontlik positiewe resultate vir metadoon of sekere mediseyne vir depressie, naamlik triksiklase antidepressante veroorsaak, wanneer sekere toetsmetodes gebruik word. selfs al neem jy nie metadoon of triksiklase antidepressante nie. Die bevestiging van die uitslae deur meer spesifieke toetse word aanbeveel.

QUESARA met voedsel en dranklee en alkohol:
QUESARA kan met of sonder voedsel geneem word. Moet nie enige alkohol drink terwyl jy QUESARA gebruik nie, aangesien die alkohol saam met QUESARA jou lomerig kan maak.
Pomelosap moet vermy word.

Swangerskap, bere voeding en fertiliteit
As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter. apteker of ander gesondheidsorgwerker vir advies voordat jy QUESARA neem.
Jy moet nie QUESARA gedurende swangerskap gebruik nie.
QUESARA moet nie geneem word terwyl jy borsvoed nie.

Die volgende simptome wat ontrekking kan voorstel, mag voorkom in pasgebore babas van moeders wat QUESARA in die laaste trimester (laaste drie maande van hul swangerskap) gebruik het: bewe, spierstyfheid en/of -swakheid, slaperigheid, rusteloosheid, asemhalingsprobleme en probleme met voeding. Indien jou baba enige van hierdie simptome ontwikkel, moet jy eerder jou dokter kontak.

Bestuur en gebruik van masjinerie
Slaperigheid, verminderde waaksaamheid, duiseligheid en lomerigheid is aangemeld in pasiënte wat QUESARA ontveng. As jy hierdie simptome ervaar. moet jy jou vermoë om te bestuur of om masjinerie te gebruik, evalueer.

QUESARA bevat
QUESARA bevat laktose. Pasiënte met die seldsame oorerflike toestande van laktose- of galaktose onverdraagsaamheid moet nie QUESARA gebruik nie.
QUESARA bevat laktose wat 'n invloed kan hê op die beheer van jou bloedsuiker as jy diabetes mellitus het.

3. Hoe om QUESARA te neem of te gee

- Moet nie mediseyne wat vir jou, of jou kind voorgeskryf is, met enige ander persoon deel nie.
- Neem, of gee altyd QUESARA presies soos jou dokter of apteker jou vertel het. Vra jou dokter of apteker indien jy onseker is.
- Jou dokter sal jou presies vertel hoeveel mediseyne jy moet neem, of gee, en wanneer jy dit moet neem, of gee.

Die gewone dosis is:
QUESARA word een of twee keer per dag geneem. Jou dokter kan jou daagliikse dosis tussen 150 en 800 mg per dag aanpas, afhangende van jou individuele behandeling en behoeftes.
Raadpleeg jou dokter indien jou simptome terugkeer, maar moet nie ophou om QUESARA te neem nie, tensy jou dokter jou beveel om dit te doen.
Neem die tablette met 'n voldoende hoeveelheid vloeistof (bv. een glas water). Moet nie die tablette kou nie,
Jou dokter sal jou vertel hoe lank jou behandeling met QUESARA sal duur. Moet nie met die behandeling vroeër ophou nie, indien jy onder die indruk is dat die effek van QUESARA te sterk of te swak is, praat dan met jou dokter of apteker.

As jy meer QUESARA neem of gee as wat jy moet
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaarsis nie, kontak die naaste hospitaal of gifbeheersentrum.
'n Oordosis kan verlaagde bloeddruk, verwarring, probleme met lnneming, depressie, probleme met asemhaling, slaperigheid en koma veroorsaak.

Indien jy vergeet om QUESARA te neem, of te gee
Dit is belangrik om jou QUESARA gereeld, elke dag op dieselfde tyd, te neem. Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, en gaan dan aan soos voorheen. Moet nie 'n dubbele dosis neem om dit die vergete individuele dosisse op te maak nie.

As jy ophou om QUESARA te neem of te gee
Neem QUESARA vir so lank as wat jou dokter dit aanbeveel. Moet nie ophou om QUESARA te neem nie, tensy jou dokter jou beveel om dit te doen.
As jy skielik ophou om QUESARA te gebruik, kan simptome soos sweet, onvermoë om te slaap, bewing, angs of naarheid, hoofpyn, diarree en braking voorkom. Jou dokter kan dalk voorstel dat jy die dosis geleidelik moet verminder voordat jy met die behandeling ophou.

4. Moontlike newe-effekte

QUESARA kan newe-effekte hê.
Nie alle newe-effekte wat vir QUESARA aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verslag of indien jy enige ongunstige effekte ervaar terwyl jy QUESARA neem, kontak asseblief jou gesondheidsorgverskaffer of apteker.
Indien enige van die volgende gebeur, hou op om QUESARA te neem of te gee, en kontak jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal
- Kombinasie van koors, griepagtige simptome, koeliesr, of enige ander infeksie met baie lae witbloedselaelling, 'n toestand wat agranulositose genoem word,
- 'n Erge allergiese reaksie (genaamd anafilaksie) wat asemhalingsprobleme of sluk kan veroorsaak.
- Probleem om te sluk
- Erge gevoel van lomerigheid
- 'n Kombinasie van hoë temperatuur (koors), sweet, stywe spiere, voel baie lomerig of word flou ('n versteuring genaamd "maligne neuroleptiese sindroom").
- Bloedklonte in die ere, veral in die bene (simptome sluit in swelling, pyn en roodheid in die bene), wat deur die bloedvate na die longe kan beweg en borskeapyn en probleme met asemhaling kan veroorsaak. Indien jy enige van hierdie simptome opmerk, moet jy dadelik mediese advies inwin.
- Aanvalle (stuipteekinge)

Hierdie is almal baie ernstige newe-effekte. As jy dit het, het jy moontlik 'n ernstige reaksie op QUESARA gehad. Jy benodig moontlik dringende mediese hulp of hospitaalsorg.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van die naaste hospitaal, indien jy enige van die volgende opmerk:
- Priapisme (langdurige en pynlike erekse)
- Probleme met urinering.
- Onbeheerbare bewegings, hoofdraaiklik van jou gesig of tong
- Geelverkleuring van die vel en oë (geelsug)
- Erge uitslag, blase, of rooi kolle op die vel,
- Vinnige swelling van die vel, gewoonlik rondom die oë, lippe en keel (angioedeem).
- 'n Ernstige toestand waarin blase op die vel, mond, oë en geslagsdele vorm (Stevens-Johnson-sindroom).

Hierdie is almal ernstige newe-effekte. Jy kan moontlik dringende mediese sorg benodig.

Kontak jou dokter onmiddellik of gaan na die naaste hospitaal as enige van die volgende gebeure met jou gebeur (hierdie word ook hieronder beskryf). Hierdie gebeurtenisse is skaars en word soms gesien met mediseyne wat gebruik word om geestesongesteldhede te behandel,
- Erge gevoel van slaperigheid
- Aanvalle (stuipteekinge)
- Priapisme (langdurige en pynlike erekale)

Vertel jou dokter indien jy enige van die volgende opmerk:
Algemene newe-effekte:
- Duiseligheid (kan lei tot val),
- Hoofpyn.
- Voel slapeng,
- Versteuring in spraak en taal
- Abnormale spierbewegings (Dit sluit probleme in om spierbewegings te begin, bewerigheid, 'n gevoel van rusteloosheid of spierstyfheid sonder pyn).
- Droë mond,
- Hardlywigheid,
- Omgeskrapte maag (slegte spysvertering)
- Braking

- Stakingsimptome (simptome wat voorkom wanneer jy ophou om QUESARA te gebruik) sluit in om nie te kan slaap nie (insomnie), siek voel (naarheid), hoofpyn, diarree, siek wees (braking), duiseligheid en liggeraaktheid. Geleidelike ontrekking oor 'n tydperk van ten minste 1 tot 2 weke word aanbeveel.
- Voel swak,
- Arms of bene wat swel.
- Voel gefrikteerd.
- Koors
- Toename in gewig,
- Veranderings in die hoeveelheid van sekere vette (triglisiriede en totale cholesterol), verhoogde bloedsuikervlakke,
- Voel meer honger
- Vinnige hartklop, voel asof jou hart bons, jeug of slae oorslaan,
- Lae bloeddruk wanneer jy opstaan.
- Dowwe wee
- Abnormale drome en nagmerries, gedagtes van selfmoord en verergering van jou depressie.
- Kort van asem, toe neus, veranderinge in die aantal tiroïechormone en jou bloed
- Toename in die aantal prolaktienhormoon in die bloed. Verhogings in die prolaktienhormoon kan in seldsame gevalle lei tot die volgende:
  - Mans en vrouens met geswelde borste en onverwagte produksie van borsmelk.
  - Vrouens met geen maandstonde, of ongereelde maandstondes.
- Afname in die hoeveelheid van sekere liipe bloedsuikers.
- Stygting in die hoeveelheid lewerensieme wat in die bloed gemeet word.

Minder algemene newe-effekte:
- Aanvalle of stuipteekinge,
- onaangename sensasies in die bene (ook bekend as rustelose bene sindroom)
- onbeheerbare bewegings, hoofraaiklik van jou gesig of long.
- Floutes (wat kan lei tot val)
- Allergiese reaksies wat verhewe bulte (galbulte), swelling van die vel en swelsel om die mond kan insluit,
- Kombinasie van koors, griepagtige simptome, seerkeel, of enige ander infeksie met baie lae witbloedselaelling, 'n toestand wat agranulositose genoem word.
- 'n Ernstige allergiese reaksie (genaamd anafilaksie) wat probleme met asemhaling of sluk kan veroorsaak.
- Probleme met sluk,
- Ontsteking van die penkrees,
- Dermobestuiste,
- Seksuele disfunksie,
- 'n Langdurige en pynlike erekale (priapisme),
- Geswelde borste en onverwagte produksie van borsmelk (galaktorree),
- menstruasionderversteuring,
- Diabetes,
- Verergering van bestaande diabetes,
- Vermindering in die hoeveelheid natrium in die bloed
- 'n Toestand (bekend as "metabolieses sindroom") waar jy moontlik 'n kombinasie van 3 of meer van die volgende kan hê: 'n toename in vet rondom jou buik, 'n afname in "goeie cholesterol" (HDL-C), 'n toename in 'n tipe vet in jou bloed, naamlik triglisiriedte, hoë bloeddruk en 'n toename in jou bloedsuiker,
- Veranderinge in elektriese aktiwiteit van die hart soos gesien op 'n EKG (QT verlenging), 'n stadiger as normale hartrempo wat kan voorkom wanneer behandeling begin word, en wat geassesseerd kan wees met lae bloeddruk en floutjies word,
- Probleme om te urineer,
- Afname in die hoeveelheid rooibloedselle.
- 'n Kombinasie van hoë temperatuur (koors), sweet, stywe spiere, voel baie lomerig of word flou ('n versteuring genaamd "maligne neuroleptiese sindroom"),
- Afname in liggaamstemperatuur (hipotermie),
- Geelverkleuring van die vel en oë (geelsug),
- ontsteking van die lewer (hepatitis),
- Bloedklonte in die ere, veral in die bene (simptome sluit in swelling, pyn en roodheid in die been), wat deur die bloedvate na die longe kan beweg en borskeapyn en probleme met asemhaling kan veroorsaak. Indien jy enige van hierdie simptome opmerk, moet jy onmiddellik mediese advies inwin.
- Loop rond, praat, eet of doen ander aktiwiteite terwyl jy aan die slaap is.
- Verhoogde kreatiefosfokinase in die bloed ('n stof vanuit die spiere),
- Ernstige uitslag, blase of rooi kolle op die vel,
- Vinnige swelling van die vel, gewoonlik rondom die oë, lippe en keel (angioedeem),
- 'n Ernstige toestand waarin blase op die vel, mond, oë en geslagsdele voortkom (Stevens-Johnson sindroom)
- Onvoldoende afskeiding van 'n hormoon wat die urienvolume beheer.
- Afbreek van spierweefsels en pyn in die spiere (rabdomiolise)

Newe-effekte waarvan die frekwensie nie bekend is nie:
- Vakuitasie met onwillekeurige mov-ekkie (veelvuldige artisem),
- Ernstige, skielike allergiese reaksie met simptome soos koors en blase op die vel en afskilfering van die vel (toksiese epidermale nekrolise),
- Geneesmiddelreaksie met eosinofilie en sistemiese simptome ("DRESS") wat beteken uit griepagtige simptome met 'n uitslag, koors, geswelde kliere en abnormale bloedtoetsresultate (insluitend verhoogde witbloedselle (eosinofilie) en lewersiekte),
- Ontrekkingsimptome kan voorkom in pasgebore babas van moeders wat QUESARA gedurende hul swangerskap gebruik het.
- Beroerte

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsluk genoem word nie, moet jy jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte
Indien jy of jou kind newe-effekte kry, praat met jou dokter, apteker of verpleegkundige.

Dit sluit enige moontlike newe-effekte in, wat nie in hierdie inligtingsblad gelys is nie. Jy kan ook newe-effekte aanmeld by SAHPRA via die "8.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van QUESARA te voorsien.

5. Hoe om QUESARA te berg

Bewaar alle mediseyne buite bereik van kinders.
Bewaar by of benede 25°C.
Bewaar die stuipstrook in die karton totdat dit benodig word vir gebruik.
Hou die HDPE houer dig gesluit.
Bewaar in die oorspronklike verpakking om sodoende van lig en vog te beskerm.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die etiket/kartonfbottel gebruik nie.
Neem alle ongebruikte mediseyne terug na jou apteker.
Moet nie ongebruikte mediseyne in die riool of rioolstelsel (bv. toilet) gooi nie.

6. Inhoud van die pak en ander inligting

Wat QUESARA bevat
QUESARA 25 mg:
Die aktiewe bestanddeel is 25 mg kwetiapien (as kwetiapienfumaraat).
QUESARA 100 mg:
Die aktiewe bestanddeel is 100 mg kwetiapien (as kwetiapienfumaraat).
QUESARA 200 mg:
Die aktiewe bestanddeel is 200 mg kwetiapien (as kwetiapienfumaraat).
QUESARA 300 mg:
Die aktiewe bestanddeel is 300 mg kwetiapien (as kwetiapienfumaraat).

Die ander bestanddele is mikrokristallyne sellulose, dibasiese kalsiumfosfaat, natriumstysselglikolaat, laktosemonohidraat, povidoon, kolloïdale silikondioksied, magnesiumstearaat, Die tablette is bedek met bedekking wat saamgestel is uit hipromellose, titaandioksied (Kleurindeks No.: 77891), en poliëtileenglikol 400.
QUESARA 25 mg bevat ook geel yelerokside (Kleurindeks No.: 77492) rooi yelerokside (Kleurindeks No.: 77491) en **QUESARA 100 mg bevat geel yelerokside** (Kleurindeks No.: 77492),
QUESARA 25 mg bevat suiker (5,175 mg laktosemonohidraat),
QUESARA 100 mg bevat suiker (20,70 mg laktosemonohidraat),
QUESARA 200 mg bevat suiker (41,40 mg laktosemonohidraat),
QUESARA 300 mg bevat suiker (62,10 mg laktosemonohidraat).

Hoe QUESARA lyk en die inhoud van die pak
QUESARA 25 mg
Persiekkleurige, ronde, filmbedekte tablette, met 'F 71' op die een kant gedruk en onverseker aan die ander kant.
QUESARA 100 mg
Geelkleurige, ronde. filmbedekte tablette, met 'F 73' op die een kant gedruk en onverseker aan die ander kant.
QUESARA 200 mg
Wilgeskleurde, ronde, filmbedekte tablette, met 'F 75" op die een kant gedruk en onverseker aan die ander kant.
QUESARA 300 mg
Wilgeskleurde, kapsuulvormige, filmbedekte tablette, met 'F 76" op die een kant gedruk en onverseker aan die ander kant.
QUESARA 25 mg:
1) **Stuipverpakking:**
Tablette word verpak in wit onderuigtige PVC/PVdC 250/60 PVC-film, bedek met 60 gsm PVdC as die vormingsmateriaal, en gewone 25 mikron, aluminiumfoelie, 6-8 gsm HSL, as die delsmateriaal. Elke stuipstrook bevat 10 tablette.
Verpakkingsgrootte: 100's – Elke karton bevat 10 stuipstroke van 10 tablette elk.
90's – Elke karton bevat 9 stuipstroke van 10 tablette elk.
2) **HDPE houer verpakking:**
Die tablette is verpak in 'n wit, ronde 60 ml HDPE-bottel met 'n 33 naksitwerking en geslut met 'n 33 mm kinderbestande sluiting met pulp en hitte seël. Elke houer bevat 100 tablette.
Verpakkingsgrootte: 100's – Een HDPE houer bevat 100 tablette.

QUESARA 100 mg:
1) **Stuipverpakking:**
Tablette word verpak in wit onderuigtige PVC/PVdC 250/60 PVC-film, bedek met 60 gsm PVdC as die vormingsmateriaal, en gewone 25 mikron, aluminiumfoelie, 6-8 gsm HSL, as die delsmateriaal. Elke stuipstrook bevat 10 tablette.
Verpakkingsgrootte: 100's – Elke karton bevat 10 stuipstroke van 10 tablette elk.
90's – Elke karton bevat 9 stuipstroke van 10 tablette elk.
2) **HDPE houer verpakking:**
Die tablette is verpak in 'n wit, ronde 60 ml HDPE-bottel met 'n 33 naksitwerking en geslut met 'n 33 mm kinderbestande sluiting met pulp en hitte seël. Elke houer bevat 100 tablette.
Verpakkingsgrootte: 100's – Een HDPE houer bevat 100 tablette

QUESARA 200 mg:
1) **Stuipverpakking:**
Tablette word verpak in wit onderuigtige PVC/PVdC 250/60 PVC-film, bedek met 60 gsm PVdC as die vormingsmateriaal, en gewone 25 mikron, aluminiumfoelie, 6-8 gsm HSL, as die delsmateriaal. Elke stuipstrook bevat 10 tablette.
Verpakkingsgrootte: 100's – Elke karton bevat 10 stuipstroke van 10 tablette elk.
60's – Elke karton bevat 6 stuipstroke van 10 tablette elk.
2) **HDPE houer verpakking:**
Die tablette is verpak in 'n wit, ronde 60 ml HDPE-bottel met 'n 38-400 naksitwerking en geslut met 'n 38 mm kinderbestande sluiting met pulp en hitte seël, Elke houer bevat 100 tablette.
Verpakkingsgrootte: 100's – Een HDPE houer bevat 100 tablette.

QUESARA 300 mg:
1) **Stuipverpakking:**
Tablette word verpak in wit onderuigtige PVC/PVdC 250/60 PVC-film, bedek met 60 gsm PVdC as die vormingsmateriaal, en gewone 25 mikron, aluminiumfoelie, 6-8 gsm HSL, as die delsmateriaal. Elke stuipstrook bevat 10 tablette.
Verpakkingsgrootte: 90's – Elke karton bevat 9 stuipstroke van 10 tablette elk.
60's – Elke karton bevat 6 stuipstroke van 10 tablette elk.
2) **HDPE houer verpakking:**
Die tablette is verpak in 'n wit ronde 75 ml HDPE-bottel met 'n 38-400 naksitwerking en geslut met 'n 38 mm kinderbestande sluiting met pulp en hitte seël, Elke houer bevat 60 tablette.
Verpakkingsgrootte: 60's – Een HDPE houer bevat 60 tablette.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Ede).
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Hierdie inligtingsblad is laas hersien in:
09 Februarie 2021

Registrasie nommer
QUESARA 25 mg: 47/2.6.5/0144
QUESARA 100 mg: 47/2.6.5/0145
QUESARA 200 mg: 47/2.6.5/0146
QUESARA 300 mg: 47/2.6.5/0147

Vir die ooreenstemmende Professionele inligting
Die oorenstemmende professionele inligting kan by https://macleodsspaproducts.co.za/ verkry word of deur 011 882 1169 te kontak

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclude Professional Information & Dimension change.

1. Product: QUESARA (Quetiapine Tablets)	
2. Country: South Africa	3. Packaging component: Package Insert & Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 GSM Bible Paper	
7. Machine Layout No.: NA	8. Dimensions: 435 (L) x 380 (W) mm
9. Design / Style: Booklet Type	10. Item code No.: PM03625802
11. Artwork has been made: Actual Size	12. Pharma code No.: 33052 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM03625801
15. Revision No: 01	16. A/W File name: X:\Quetiapine\SA Private Market\01\Quetiapine Tablets PIL- PM03625802.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
26/06/23	Vanita Rajool	27/06/23	30/06/23	1/07/23	Cyadav 04/07/23

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM03625801	17/08/22	02/01/23
2) Exclude Professional Information & Dimension change.	PM03625802		

CONTROLLED COPY ISSUED TO QP

Sign.: Date: 26/04/24