QUESARA XR (Quetiapine XR Tablets) Front

440 mm

300 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

QUESARA XR 150 mg (extended-release tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 74,25 mg)
QUESARA XR 200 mg (extended-release tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 99,0 mg)
QUESARA XR 300 mg (extended-release tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 148,5 mg)
QUESARA XR 400 mg (extended-release tablet)
Quetiapine fumarate
Contains sugar (Lactose monohydrate 198,0 mg)

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

1. What QUESARA XR is and what it is used for

QUESARA XR belongs to a group of medicines called antipsychotics.
QUESARA XR 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. It is also used to prevent relapse in stable schizophrenic patients who have been maintained on **QUESARA XR**.
QUESARA XR is used to treat bipolar disorder including mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive. It is also used to prevent recurrence in the maintenance of bipolar disorder.

2. What you need to know before you take QUESARA XR

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

QUESARA XR should not be given to children and adolescents, as safety and efficacy have not been demonstrated.

Warnings and precautions
Take special care with **QUESARA XR**:
Tell your doctor or healthcare professional before you take **QUESARA XR**:
- 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 disorders
- 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 or have had a condition where you stop breathing for short periods during your normal nightly sleep (called "sleep apnoea") and are taking medicines that slow down the normal activity of the brain ("depressants").
- If you have difficulty swallowing or are at risk of getting food or liquid into your lungs.
- 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 are an elderly person with Parkinson's disease/parkinsonism.
- if you have an enlarged prostate, have bowel obstruction or eye problems (increased pressure in the eyes or glaucoma)
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- if you have a history of alcohol or drug abuse.

While taking **QUESARA XR**:
- Thoughts of suicide:
  You may sometimes have thoughts of harming or killing yourself when you suffer from the psychiatric condition for which **QUESARA XR** has been prescribed to you (see section 1). These may be increased when first starting treatment, since **QUESARA XR** 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 about your condition and ask them to read this leaflet. You might ask them to tell you if they think your condition is getting worse, or if they are worried about changes in your behaviour.

Tell your doctor:
- If you observe sudden infections. This can happen because of decreased white blood cell count in your blood, which leads to decreased immunity.
- If you observe symptoms like excessive thirst, eating and urination. **QUESARA XR** can cause high blood sugar levels and in some cases could result in coma or death. 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 XR**. Your doctor will do blood tests to check certain fat levels before you start taking **QUESARA XR** and regularly during treatment.
- Weight gain has been seen in patients taking **QUESARA XR**. You and your doctor should check your weight regularly.
- If you feel symptoms like indigestion, nausea, vomiting and loss of appetite. **QUESARA XR** may cause inflammation of the pancreas (pancreatitis).
- 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.
- If you suffer from sleep disorders. **QUESARA XR** may cause sleep apnoea which is a potentially serious sleep disorder in which breathing repeatedly stops and starts.
- If you experience coughing, difficulty breathing and in some cases choking. **QUESARA XR** may cause difficulty on swallowing and a condition in which food, liquids, saliva or vomit is breathed into the airways.
- If you experience abdominal pain followed by difficulty in passing stools (constipation).
- If you experience unusual movements mainly of the face or tongue.
- If you experience 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.
- If you have a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness.
- If you experience sleepiness, nausea, vomiting, headache, diarrhoea if you suddenly stopping treatment with **QUESARA XR**. Your doctor will gradually reduce your dose over one or two weeks to prevent withdrawal symptoms.
- If you experience an increase in prolactin levels characterized 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 XR
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
You might feel drowsy if **QUESARA XR** 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 (used to treat depression)
- Cimetidine (used to treat gastric ulcers)
- 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.

QUESARA XR with food and drink and alcohol
QUESARA XR can be taken with or without food. Do not drink any alcohol while taking **QUESARA XR** as the alcohol together with **QUESARA XR** 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 XR**.

You should not take **QUESARA XR** during pregnancy.
You should not breastfeed your baby if you are taking **QUESARA XR**.

Fertility
The effects of quetiapine on human fertility have not been assessed. Effects related to elevated prolactin levels were seen in rats, although these are not directly relevant to humans.

Driving and using machines
Sleepiness, decreased alertness, dizziness and drowsiness have been reported in patients receiving **QUESARA XR**. If you experience these you should not drive or operate machinery.

QUESARA XR contains
QUESARA XR contains lactose. If you have been told by your doctor that you have conditions of lactose or galactose intolerance you should not take **QUESARA XR**.

4. How to take or give QUESARA XR

- Do not share medicines prescribed for you or your child with any other person.
- Always take or give **QUESARA XR** 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 XR is taken once daily, with or without food. 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 XR** 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 XR** will last. Do not stop treatment early. If you have the impression that the effect of **QUESARA XR** is too strong or too weak, tell your doctor or pharmacist.

If you take or give more QUESARA XR 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 XR
It is important to take your **QUESARA XR** 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 XR
Take **QUESARA XR** for as long as your doctor recommends. Do not stop taking **QUESARA XR** unless your doctor tells you to.
If you suddenly stop taking **QUESARA XR**, 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 XR can have side effects.
Not all side effects reported for **QUESARA XR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **QUESARA XR**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking or giving **QUESARA XR** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Allergic reaction or symptoms of a severe allergic reaction such as:
  - Swelling of face, tongue or throat.
  - Difficulties in swallowing.
  - Hives and difficulties in breathing.
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Rash with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome)
- Severe skin reactions that can include blistering of the skin.
- 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.
- Thoughts of suicide.

These are all very serious side effects. If you have them, you may have had a serious reaction to **QUESARA XR**. 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:
- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called "neuroleptic malignant syndrome").
- Lowering of normal body temperature.
- Seizures.
- Abnormal rhythms of the heart.
- Stroke.
- Inflammation of the pancreas causing severe stomach pain, fever and sickness.
- Liver disease appearing as yellowing of the skin and white parts of the eyes.
- Muscle disease presenting as unexplained aches and pains.
- Difficulty in passing urine.
- Prolonged and/or painful erection.

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:
- Weight gain and increased appetite.
- Sleepiness, dizziness, headache, fainting, problems with speech, unusual movement (especially of the face or tongue).
- Increases in the levels of prolactin in the blood.
- Abnormal dreams and nightmares
- Blurred vision
- Palpitations (feeling like your heart is pounding, racing or has skipped beats)
- Dry mouth, constipation, indigestion, vomiting.
- Weakness, swelling of the hands and feet, irritability, fever, withdrawal symptoms (symptoms which occur when you stop taking **QUESARA XR** include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, vomiting, dizziness and irritability.
- Stuffy nose, increased cough, shortness of breath.
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Less frequent side effects:
- Changes in the levels of some blood cells, bruising, enlarged lymph nodes, bluish or purplish discolouration of the skin or mucous membranes, destruction of red blood cells.
- Changes in the amount of thyroid hormones in your blood, diabetes, high levels of a certain hormone causing the body to retain water.
- Decrease in sodium levels in the blood, worsening of pre-existing diabetes, a condition (called "metabolic syndrome") where you 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.
- Walking, talking, eating or other activities while you are asleep.
- Unpleasant sensations in the legs (also called restless legs syndrome), involuntary movements which you cannot control.
- Glaucoma, dry eyes.
- Ear pain.
- Change in electrical activity of the heart seen on ECG (QT prolongation), a slower than normal heart rate.
- High blood pressure.
- Difficulty swallowing, bowel obstruction.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis), muscle pain.
- Urinary tract infection.
- Symptoms of withdrawal may occur in newborn babies of mothers that have used **QUESARA XR** during their pregnancy.
- Swelling of breasts and unexpected production of breast milk (galactorrhoea), menstrual disorder.
- Stomach pain, back pain.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.

Laboratory tests may show:
- Changes in the amount of thyroid hormones in your blood.
- Decreases in the number of certain types of blood cells.
- 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.
- Increases in the amount of liver enzymes measured in the blood.

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 "**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 **QUESARA XR**.

5. How to store QUESARA XR

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 XR contains
QUESARA XR 150 mg
The active substance is 150 mg quetiapine (as quetiapine fumarate).
QUESARA XR 200 mg
The active substance is 200 mg quetiapine (as quetiapine fumarate).
QUESARA XR 300 mg
The active substance is 300 mg quetiapine (as quetiapine fumarate).
QUESARA XR 400 mg
The active substance is 400 mg quetiapine (as quetiapine fumarate).

The other ingredients are microcrystalline cellulose, lactose monohydrate, sodium citrate dihydrate, ethylcellulose, povidone, isopropyl alcohol, magnesium stearate.
QUESARA XR 150 mg and 400 mg tablets are coated with coating made up of hypromellose, titanium dioxide (Colour Index No. 77891), polyethylene glycol 400,
In addition **QUESARA XR 200 mg** and **300 mg** contain iron oxide yellow (Colour Index No.:77492).
QUESARA XR 150 mg contains sugar (lactose monohydrate 74,25 mg).
QUESARA XR 200 mg contains sugar (lactose monohydrate 99,0 mg).
QUESARA XR 300 mg contains sugar (lactose monohydrate 148,5 mg).
QUESARA XR 400 mg contains sugar (lactose monohydrate 198,0 mg).

What QUESARA XR looks like and contents of the pack
QUESARA XR 150 mg
White to off white coloured, capsule shaped, film coated tablets debossed with 'C 22' on one side and plain on the other side.

QUESARA XR 200 mg
Yellow coloured, capsule shaped, film coated tablets debossed with 'C 23' on one side and plain on the other side.

QUESARA XR 300 mg
Pale yellow coloured, capsule shaped, film coated tablets debossed with 'C 24' on one side and plain on the other side.

QUESARA XR 400 mg
White to off white coloured, capsule shaped, film coated tablets debossed with 'C 25' on one side and plain on the other side.

QUESARA XR 150, 200, 300 and 400 mg:
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 µm, aluminium foil, 6-8 gsm HSL, as the lidding material.
Pack size:
QUESARA XR 150 mg: 10's, 30's, 60's or 100's
QUESARA XR 200, 300 and 400 mg: 10's, 60's or 100's

HDPE Container Pack:
Tablets are packed in white, opaque, round 40 ml/60 ml/100 ml/120 ml HDPE bottle closed with a white child resistant closure with pulp and heat seal.
Pack size: 60's - One HDPE container contains 60 tablets.
Not all 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.

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11 May 2021

Registration numbers:
QUESARA XR 150 mg: 48/2.6.5/0076
QUESARA XR 200 mg: 48/2.6.5/0077
QUESARA XR 300 mg: 48/2.6.5/0078
QUESARA XR 400 mg: 48/2.6.5/0079

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

QUESARA XR
Quetiapine XR Tablets
PM04342260

QUESARA XR (Quetiapine XR Tablets) Back

440 mm

300 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

QUESARA XR 150 mg (verlengde-vrystelling tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 74,25 mg)
QUESARA XR 200 mg (verlengde-vrystelling tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 99,0 mg)
QUESARA XR 300 mg (verlengde-vrystelling tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 148,5 mg)
QUESARA XR 400 mg (verlengde-vrystelling tablet)
Kwetiapienfumaraat
Bevat suiker (Laktosemonohidraat 198,0 mg)

Lees hierdie hele inligtingsblad aandagtig deur, voordat jy QUESARA XR 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 XR** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander 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 XR** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **QUESARA XR** gebruik.
3. Hoe om **QUESARA XR** te gebruik
4. Moontlike newe-effekte
5. Hoe om **QUESARA XR** te berg
6. Inhoud van die pak en ander inligting

1. Wat QUESARA XR is en waarvoor dit gebruik word

QUESARA XR behoort aan 'n groep medisyne wat antipsigotiese middels genoem word.
QUESARA XR word gebruik om skisofrenie te behandel met simptome soos om dinge wat nie bestaan nie te hoor, te sien, of aan te voel, verkeerde oortuigings, ongewone agterdog, en teruggetrokkenheid. Dit word ook gebruik as voorkoming van relaps in stabiele skisofreniese pasiënte wat op **QUESARA XR** in stand gehou is.
QUESARA XR word gebruik om bipolêre versteuring, insluitende manie: waar jy baie opgewonde, uitgelate, rusteloos, entoesiasties of hiperaktief kan voel of swak oordeel het, insluitende aggressief of ontwrigtend. Dit word ook gebruik om herhaling in die instandhouding van bipolêre versteuring te voorkom.

2. Wat jy behoort te weet voordat jy QUESARA XR neem

Moet nie QUESARA XR neem nie:
- indien jy allergies vir kwetiapien of enige van die ander bestanddele van **QUESARA XR** is.
- indien jy swanger is of borsvoed, aangesien veiligheid nog nie vasgestel is nie
- indien jy 'n gevorderde lewer- of niersiekte het, aangesien veiligheid nog nie vasgestel is nie
- indien jy die volgende medisyne gebruik:
  - amprenavir, indinavir, nelfinavir, ritonavir en sakwinavir (vir MIV behandeling),
  - itrakonasool, ketokonasool (swambestrydende medisyne)
  - eritromisien, klaritromisien (vir infeksies) en nefasadoon (vir depressie)

QUESARA XR moet nie aan kinders en adolessente gegee word nie, aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **QUESARA XR**:
Vertel jou dokter of gesondheidsorgverskaffer voordat jy **QUESARA XR** neem:
- oor enige mediese probleme in die verlede of tans
- oor enige allergieë wat jy het of gehad het
- indien jy swanger is of jou kind borsvoed
- as jy 'n nier- of lewersiekte het
- indien jy aan enige bloedversteurings ly
- as jy onlangs 'n beroerte gehad het
- indien jy diabetes het
- as jy lae of hoë bloeddruk het, 'n familie geskiedenis van hartsiekte, byvoorbeeld probleme met hartritme, verswakking van die hartspier of inflammasie van die hart, of indien jy enige medisyne neem wat moontlik 'n invloed kan hê op die manier waarop jou hart klop.
- as jy 'n toestand het of gehad het waar jy vir kort rukkies ophou asemhaal het gedurende jou normale nagtelike slaap (bekend as "slaapapnee") en medisyne gebruik wat die normale aktiwiteit van die brein vertraag ("onderdrukkers").
- indien jy sukkel om te sluk of die gevaar loop om voedsel of vloeistof in jou longe te kry.
- as jy epilepsie het
- as jy 'n bejaarde persoon is en ly aan demensie (geestesongesteldheid) gekarakteriseer deur 'n afname in geheue, spraak, probleemoplossing en ander denkvaardighede wat 'n persoon se vermoë om daaglikse take uit te voer, beïnvloed.
- indien jy 'n bejaarde persoon is met Parkinson se siekte/parkinsonisme.
- as jy 'n vergrote prostaat het, 'n obstruksie in jou derms of oogprobleme (verhoogde druk in die oë of gloukoom)
- indien jy of iemand anders in jou familie 'n geskiedenis het van bloedklonte, aangesien medisyne soos hierdie al geassosieer is met die vorming van bloedklonte.
- indien jy 'n geskiedenis van alkohol- of dwelmmisbruik het.

Terwyl **QUESARA XR** geneem word:
- Gedagtes van selfmoord:
  Jy kan soms daaraan dink om jouself leed aan te doen of om jou eie lewe te neem as jy ly aan die psigiatriese toestand waarvoor **QUESARA XR** vir jou voorgeskryf is (sien afdeling 1). Hierdie gedagtes kan toeneem wannneer daar met die behandeling begin word, omdat **QUESARA XR** 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 kan dit nuttig vind om 'n familielid of hegte vriend te vertel dat jy depressief is en hulle te vra om hierdie inligtingsblad te lees. Jy kan hulle vra om jou te sê wanneer hulle dink dat jou toestand erger word, of as hulle bekommerd is oor veranderinge in jou gedrag.

Vertel jou dokter:
- Indien jy skielike infeksies waarneem. Dit kan gebeur as gevolg van die verminderde aantal witbloedselle in jou bloed, wat lei tot verlaagde immuniteit.
- Indien jy simptome soos oormatige dors, eet en urinering waarneem. **QUESARA XR** kan hoë bloedsuikervlakke veroorsaak en in sommige gevalle tot 'n koma of die dood lei. Jou dokter sal jou bloedsuikervlakke op 'n gereelde basis monitor en jou behandel vir die hoë bloedsuiker.
- Hoë vlakke van vet (trigliseriede en cholesterol) in die bloed is al gesien in pasiënte wat **QUESARA XR** gebruik. Jou dokter sal bloedtoetse doen om sekere vette se vlakke te kontroleer, voordat jy begin om **QUESARA XR** te neem en gereeld tydens die behandeling.
- Gewigstoename is gesien in pasiënte wat **QUESARA XR** gebruik. Jy en jou dokter moet jou gewig gereeld kontroleer.
- Indien jy simptome soos slegte spysvertering, naarheid, braking en verlies aan eetlus ervaar.
  QUESARA XR kan ontsteking van die pankreas (pankreatitis) veroorsaak.
- As jy ligh oofdigheid of floutes ervaar, veroorsaak deur die skielike verandering in harttempo en bloeddruk, wanneer jy te vinnig vanuit 'n sit- of lêposisie opstaan.
- Indien jy aan slaapversteurings ly. **QUESARA XR** kan slaapapnee veroorsaak, wat 'n moontlike ernstige slaapafwyking is waarin asemhaling herhaaldelik ophou en begin.
- Indien jy hoes, moeilik asemhaal en in sommige gevalle verstik. **QUESARA XR** kan dit moeilik maak om te sluk en 'n toestand veroorsaak waarin voedsel, vloeistowwe, speeksel of braaksel in die lugweë ingeasem word.
- As jy abdominale pyn ervaar, gevolg deur probleme met ontlasting (hardlywigheid).
- Indien jy ongewone bewegings ervaar, meestal van jou gesig of tong.
- As jy erge rusteloosheid ervaar, met die behoefte daaraan om te beweeg, wat gewoonlik gepaardgaan met die onvermoë om stil te sit of stil te staan, veral gedurende die eerste paar weke van die behandeling.
- Indien jy 'n kombinasie van koors, vinniger asemhaling, sweet, spierstyfheid en lomerigheid of slaperigheid het.
- As jy slaperigheid, naarheid, braking, hoofpyn, diarree ervaar wannneer jy skielik met **QUESARA XR** behandeling ophou. Jou dokter sal jou dosis geleidelik oor een of twee weke verminder om onttrekkingsimptome te voorkom.
- Indien jy 'n toename in prolaktienvlakke ervaar, wat gekenmerk word deur onreëlmatige of afwesige maandstondes, onvrugbaarheid, menopousale simptome (warm gloede en vaginale droogheid), en na 'n paar jaar, osteoporose (verdunning en verswakking van die bene). Hoë prolaktienvlakke kan ook melkafskeiding uit die borste veroorsaak.

Ander medisyne en QUESARA XR
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Jy kan lomerig voel wanneer **QUESARA XR** geneem word in kombinasie met alkohol, antidepressante of medisyne wat gebruik word vir angstigheid of om jou te help slaap (kalmeermiddels).
Stel jou dokter in kennis indien jy die volgende medisyne neem:
- Ketokonasool, flukonasool of itrakonasool (vir swambesmetting)
- Fenitoïen, natriumvalproaat of karbamasepien (vir epilepsie)
- Levodopa (vir Parkinson se siekte)
- Imipramien en fluoksetien (gebruik om depressie te behandel)
- Simetidien (gebruik om gastriese ulkusse te behandel)
- Litium (ander antipsigotiese middels)
- Risperidoon, haloperidol en tioridasien (antipsigotiese middels)
- Medisyne wat 'n invloed het op die manier waarop jou hart klop, byvoorbeeld medisyne wat 'n wanbalans in elektroliete (lae kalium- of magnesiumvlakke) kan veroorsaak, soos diuretika (waterpille) of sekere antibiotika (om infeksies te behandel).
- Medisyne (naamlik "anticholinergiese middels") wat die wyse waarop senuweeselle funksioneer beïnvloed, om sodoende sekere mediese toestande te behandel.

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

Swangerskap, borsvoeding en fertiliteit
As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **QUESARA XR** gebruik.

Jy moet nie **QUESARA XR** gedurende swangerskap gebruik nie.
Jy moet nie jou baba borsvoed terwyl jy **QUESARA XR** gebruik nie.

Fertiliteit
Die uitwerking van kwetiapien op menslike vrugbaarheid is nie vasgestel nie. Effekte wat verband hou met verhoogde prolaktienvlakke is in rotte gesien, hoewel dit nie direk relevant is vir mense nie.

Bestuur en gebruik van masjinerie
Slaperigheid, verminderde waaksaamheid, duiseligheid en lomerigheid is aangemeld in pasiënte wat **QUESARA XR** ontvang. Indien jy hierdie simptome ervaar, moet jy nie bestuur of masjinerie gebruik nie.

QUESARA XR bevat
QUESARA XR bevat laktose. Indien jou dokter jou meegedeel het dat jy toestande van laktose- of galaktose onverdraagsaamheid het, moet jy nie **QUESARA XR** neem nie.

3. Hoe om QUESARA XR te neem of te gee

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

Die gewone dosis is:
QUESARA XR word een keer per dag geneem, met of sonder voedsel. Jou dokter kan jou daaglikse 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 XR** 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 XR** sal duur. Moet nie vroeër met die behandeling ophou nie. As jy onder die indruk is dat die effek van **QUESARA XR** te sterk of te swak is, praat dan met jou dokter of apteker.

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

As jy vergeet om QUESARA XR te neem, of te gee
Dit is belangrik om jou **QUESARA XR** 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 vir die vergete individuele dosisse op te maak nie.

As jy ophou om QUESARA XR te neem of te gee
Neem **QUESARA XR** vir so lank as wat jou dokter dit aanbeveel. Moet nie ophou om **QUESARA XR** te neem nie, behalwe as jou dokter jou beveel om dit te doen.
Indien jy skielik ophou om **QUESARA XR** 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 XR kan newe-effekte hê.
Nie alle newe-effekte wat vir **QUESARA XR** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl jy **QUESARA XR** neem, kontak asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **QUESARA XR** te neem of te gee, en kontak jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Allergiese reaksie of simptome van 'n ernstige allergiese reaksie soos:
  - Swelling van die gesig, tong of keel.
  - Probleme met sluk.
  - Netelroos en probleme met asemhaling.
- Wydverspreide uitslag, hoë liggaamstemperatuur, verhoogde lewerensieme, bloedabnormaliteite (eosinofilie), geswelde limfkliere en ander liggaamsorgane se betrokkenheid (Geneesmiddeluitslag met eosinofilie en sistemiese simptome wat ook bekend staan as "DRESS" of geneesmiddel hipersensitiwiteit sindroom).
- Ernstige velreaksies wat blase van die vel kan insluit.
- Bloedklonte in die are, veral in die bene (simptome sluit in swelling, pyn en rooiheid in die been), wat deur die bloedvate na die longe kan beweeg en borskaspyn en moeilike asemhaling kan veroorsaak.
- Gedagtes van selfmoord.

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

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal, indien jy enige van die volgende opmerk:
- n Kombinasie van 'n hoë temperatuur, (koors), sweet, stywe spiere, erge lomerige gevoel of floute ('n versteuring genaamd "maligne neuroleptiese sindroom").
- Verlaging van normale liggaamstemperatuur.
- Aanvalle.
- Abnormale hartritme.
- Beroerte.
- Ontsteking van die pankreas wat erge maagpyn, koors en siekte tot gevolg het.
- Lewersiekte kom voor as geelwording van die vel en wit dele van die oë.
- Spiersiekte, in die vorm van onverklaarbare pyne en skete.
- Probleme met urinering.
- Langdurige en/of pynlike ereksie.

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

Vertel jou dokter indien jy enige van die volgende opmerk:
Algemene newe-effekte:
- Gewigstoename en toename in eetlus.
- Slaperigheid, duiseligheid, hoofpyn, floutes, probleme met spraak, ongewone bewegings (veral van die gesig of tong).
- Verhoging van die prolaktienvlakke in die bloed.
- Abnormale drome en nagmerries.
- Dowwe sig
- Hartkloppings (voel of jou hart bons, jaag of slae oorslaan)
- Droë mond, hardlywigheid, swak spysvertering, braking.
- Swakheid, swelling van die hande en voete, prikkelbaarheid, koors, onttrekkingsimptome (simptome wat voorkom wanneer jy stop om **QUESARA XR** te neem, dit sluit in om nie te kan slaap nie (insomnie), voel siek (naarheid), hoofpyn, diarree, braking, duiseligheid en prikkelbaarheid.
- Toe neus, hoes meer, kortasem.
- In die vroeë stadiums van behandeling kan sommige mense duiselig voel of flou word (met 'n stadige harttempo), veral wanneer hulle opstaan uit 'n lê- of sitposisie. Dit sal gewoonlik vanself verbygaan, maar indien dit nie gebeur nie, vertel jou dokter.

Minder algemene newe-effekte:
- Veranderinge in die vlakke van sommige bloedselle, kneusing, vergrote limfknope, blouerige- of perserige verkleuring van die vel of slymvliese, vernietiging van rooibloedselle.
- Veranderinge in die aantal skildklierhormone in jou bloed, diabetes, hoë vlakke van 'n sekere hormoon wat veroorsaak dat die liggaam water terughou.
- Afname in bloednatriumvlakke, verergering van reeds bestaande diabetes, 'n toestand (bekend as "metaboliese sindroom") waar jy 'n kombinasie van 3 of meer van die volgende het: 'n toename in vet rondom jou buik, 'n afname in "goeie cholesterol" (HDL-C), 'n toename in 'n tipe vet in jou bloed, naamlik trigliseriede, hoë bloeddruk en 'n verhoging in jou bloedsuiker.
- Loop rond, praat, eet of doen ander aktiwiteite terwyl jy aan die slaap is.
- Onaangename sensasies in die bene (ook bekend as rustelose bene sindroom), onwillekeurige bewegings wat jy nie kan beheer nie.
- Gloukoom, droë oë.
- Oorpyn.
- Verandering in elektriese aktiwiteit van die hart gesien op 'n EKG (QT verlenging), 'n stadiger as normale harttempo.
- Hoë bloeddruk.
- Probleme met sluk, dermobstruksie.
- Afbreek van spiervesels en pyn in spiere (rabdomiolise), spierpyn.
- Urienweginfeksie.
- Onttrekkingsimptome kan voorkom in pasgebore babas van moeders wat **QUESARA XR** gedurende hul swangerskap gebruik het.
- Geswelde borste en onverwagte produksie van borsmelk (galaktorree), menstruele versteurings.
- Maagpyn, rugpyn.
- Kombinasie van koors, griepagtige simptome, seer keel, of enige ander infeksie met baie lae witbloedseltelling, 'n toestand wat agranulositose genoem word.

Laboratoriumtoetse kan toon:
- Veranderinge in die hoeveelheid skildklierhormone in jou bloed.
- Afname in die aantal van sekere soorte bloedselle.
- Vermindering in "goeie cholesterol" (HDL-C), 'n toename in 'n soort vet in jou bloed wat trigliseriede genoem word, hoë bloeddruk en 'n verhoging in jou bloedsuiker.
- Toename in die hoeveelheid lewerensieme wat in die bloed gemeet word

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 "**6.04 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 XR** te voorsien.

5. Hoe om QUESARA XR te berg

Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 25°C.
Bewaar die stulpstrook 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/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die riool of rioolstelsel (bv. toilet) gooi nie.

6. Inhoud van die pak en ander inligting

Wat QUESARA XR bevat
QUESARA XR 150 mg
Die aktiewe bestanddeel is 150 mg kwetiapien (as kwetiapienfumaraat).
QUESARA XR 200 mg
Die aktiewe bestanddeel is 200 mg kwetiapien (as kwetiapienfumaraat).
QUESARA XR 300 mg
Die aktiewe bestanddeel is 300 mg kwetiapien (as kwetiapienfumaraat).
QUESARA XR 400 mg
Die aktiewe bestanddeel is 400 mg kwetiapien (as kwetiapienfumaraat).

Die ander bestanddele is mikrokristallyne sellulose, laktosemonohidraat, natriumsitraat dihidraat, etielsellulose, povidoon, isopropielalkohol, magnesiumstearaat. **QUESARA XR 150 mg** en **400 mg** tablette is bedek met bedekking wat saamgestel is uit hipromellose, titaandioksied (Kleurindeks No.: 77891), en poliëtileenglikol 400.
QUESARA XR 200 mg en **300 mg** bevat ook geel ysteroksied (Kleurindeks No.: 77492).
QUESARA XR 150 mg bevat suiker (74,25 mg laktosemonohidraat).
QUESARA XR 200 mg bevat suiker (99,0 mg laktosemonohidraat).
QUESARA XR 300 mg bevat suiker (148,5 mg laktosemonohidraat).
QUESARA XR 400 mg bevat suiker (198,0 mg laktosemonohidraat).

Hoe QUESARA XR lyk en die inhoud van die pak
QUESARA XR 150 mg
Wit- tot naaswit gekleurde, kapsuulvormige, filmbedekte tablette, met "C 22" op die een kant gedruk en onversier aan die ander kant.
QUESARA XR 200 mg
Geelkleurige, kapsuulvormige, filmbedekte tablette, met "C 23" op die een kant gedruk en onversier aan die ander kant.
QUESARA XR 300 mg
Bleekgeelkleurige, kapsuulvormige, filmbedekte tablette, met "C 24" op die een kant gedruk en onversier aan die ander kant.
QUESARA XR 400 mg
Wit- tot naaswit gekleurde, kapsuulvormige, filmbedekte tablette, met "C 25" op die een kant gedruk en onversier aan die ander kant.

QUESARA XR 150, 200, 300 en **400 mg**:
Stulpverpakking:
Tablette word verpak in wit, ondeursigtige PVC/PVdC 250/60 PVC-film, bedek met 60 gsm PVdC as die vormingsmateriaal, en gewone 25 µm, aluminiumfoelie, 6-8 gsm HSL, as die dekmateriaal.
Verpakkingsgroottes:
QUESARA XR 150 mg: 10's, 30's, 60's or 100's
QUESARA XR 200, 300 and **400 mg**: 10's, 60's or 100's

HDPE houer verpakking:
Tablette is verpak in wit, ondeursigtige, ronde 40 ml/60 ml/100 ml/120 ml HDPE-bottel, gesluit met 'n kinderbestande sluiting met pulp en hitte seël.
Verpakkingsgroottes: 60's – Een HDPE houer bevat 60 tablette.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

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

Hierdie inligtingsblad is laas hersien in:
11 Mei 2021

Registrasie nommers:
QUESARA XR 150 mg: 48/2.6.5/0076
QUESARA XR 200 mg: 48/2.6.5/0077
QUESARA XR 300 mg: 48/2.6.5/0078
QUESARA XR 400 mg: 48/2.6.5/0079

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclusion of PI from text matter as per commercial requirement and change in dimensions.

1. Product: QUESARA XR (Quetiapine XR Tablets)	
2. Country: South Africa (Private Market)	**3. Packaging component: 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: 440 (L) x 300 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04342260**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 41097 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03622401**
15. Revision no: 01	**16. A/W File name: G:\Regulated_Artwork\SOUTH AFRICA\QUESARA XR\SA Private Market\02\Quetiapine XR Tablets PIL- PM04342260.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	18/03/2026				

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 (Private Market)	PM03622401	20/08/22	21/10/22
2) Exclusion of PI from text matter as per commercial requirement and change in dimensions.	PM04342260		