AROQUET XR 50/150/200/300/400 prolonged release tablet

Strength: Each prolonged release tablet contains 50/150/200/300/400 mg quetiapine fumarate equivalent to quetiapine, respectively.

Response to Clinical Evaluation recommendation dated 30/09/2020, received letter on 9/10/2020

Response to Clinical Evaluation recommendation, received e-mail dated 19/03/2021

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SCHEDULING STATUS

S5

AROQUET XR 50/150/200/300/400 (prolonged-release tablet)

Quetiapine fumarate

Contains sugar (lactose)

Read all of this leaflet carefully before you are given AROQUET XR (prolonged-release tablet)

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

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

AROQUET XR contains a substance called quetiapine. This belongs to a group of medicines called antipsychotics. **AROQUET XR** can be used to treat several illnesses, such as:

- Schizophrenia
- Preventing relapse in stable schizophrenic patients who have been maintained on **AROQUET XR**.
- Bipolar disorder including:
  - Manic episodes associated with bipolar disorder
  - Depressive episodes associated with bipolar disorder
  - Preventing recurrence in the maintenance treatment of bipolar disorder (manic,mixed or depressive episodes) as monotherapy or in combination with mood stabilisers
- Major depressive disorder
- Preventing relapse in stable major depressive disorder patients who have been maintained on **AROQUET XR**.

2. What you need to know before you use AROQUET XR

Do not take AROQUET XR:

- If you are hypersensitive (allergic) to quetiapine or any of the other ingredients of **AROQUET XR** (listed in section 6).
- If you are taking any of the following medicines:
  - some medicines for HIV
  - azole medicines (for fungal infection)
  - erythromycin or clarithromycin (for infections)

- nefazodone (for depression).
- If you are pregnant or breastfeeding your baby.
- If you are a child (10 – 12 years) or adolescent (13 - 17 years) as safety and efficacy have not been established.
- If you suffer from advanced liver or renal dysfunction as safety has not been demonstrated.

Warnings and precautions

Talk to your doctor or pharmacist before taking AROQUET XR if:

- you are under 18 years of age (see Do not take **AROQUET XR** above].
- you, or someone in your family, have or have had any heart problems, 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.
- you have low blood pressure.
- you have had a stroke, especially if you are elderly.
- you have problems with your liver.
- you have ever had a fit (seizure).
- you have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking **AROQUET XR**.
- you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- you are an elderly person with dementia (loss of brain function). If you are, **AROQUET XR** should not be taken because the group of medicines that **AROQUET XR** belongs to

may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.

- you are an elderly person with Parkinson's disease/parkinsonism.
- 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.
- 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").
- you have or have had a condition where you can't completely empty your bladder (urinary retention), have an enlarged prostate, a blockage in your intestines, or increased pressure inside your eye. These conditions are sometimes caused by medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- you have a history of alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking **AROQUET XR**:

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.
- Uncontrollable movements, mainly of your face or tongue.
- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).

- A long-lasting and painful erection (Priapism).

These conditions can be caused by this type of medicine.

Tell your doctor as soon as possible if you have:

- A fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may **require AROQUET XR** to be stopped and/or treatment to be given.
- Constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.
- 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 these medicines all take time to work, usually about two weeks but sometimes longer. These thoughts may also be increased if you suddenly stop taking your medication. You may be more likely to think like this if you are a young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in young adults aged less than 25 years with depression. 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.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) which can be life threatening or fatal have been

reported very rarely with treatment of this medicine. These are commonly manifested by:

- Stevens-Johnson syndrome (SJS), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.
- Toxic Epidermal Necrolysis (TEN), a more severe form causing extensive peeling of the skin.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) 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).

Stop using **AROQUET XR** if you develop these symptoms and contact your doctor or seek medical attention immediately.

Weight gain

Weight gain has been seen in patients taking **AROQUET XR**. You and your doctor should check your weight regularly.

Children and adolescents

AROQUET XR is not for use in children and adolescents below 18 years of age.

Other medicines and AROQUET XR

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other

medicines, including medicines obtained without a prescription.

- Medicine that can cause constipation.
- Medicine (called “anti-cholinergics”) that affect the way nerve cells function in order to treat certain medical conditions.
- Epilepsy medicines (like phenytoin or carbamazepine).
- Thioridazine or Lithium (other 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 (medicine to treat infections).
- Barbiturates (for difficulty sleeping).

AROQUET XR with food, drink and alcohol

- **AROQUET XR** can be affected by food and you should therefore take your tablets at least one hour before a meal or prior to bedtime.
- Be careful how much alcohol you drink. This is because the combined effect of **AROQUET XR** and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking **AROQUET XR**. It can affect the way the medicine works.

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 **AROQUET XR. AROQUET XR** should not be taken during pregnancy and breastfeeding (see Do not take **AROQUET XR**).

Driving and using machines

AROQUET XR tablets may make you feel sleepy. Do not drive or use any machines until you know how the tablets affect you.

AROQUET XR contains lactose.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

3. How to use AROQUET XR

Do not share medicines prescribed for you with any other person. Always take **AROQUET XR** exactly as your doctor has instructed you. You should check with your doctor of pharmacist if you are unsure. Your doctor will decide on your starting dose. The usual dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg. You will take your tablets once a day. Do not split, chew or crush the tablets. Swallow your tablets whole with a drink of water.

E**lderly people**

If you are elderly your doctor may change your dose.

Children and adolescents

AROQUET XR should not be used in children and adolescents aged under 18 years.

Liver problems

If you have liver problems your doctor may change your dose.

Your doctor will tell you how long your treatment with **AROQUET XR** will last. Do not stop taking your tablets even if you feel better, unless your doctor tells you. If you have the impression that the effect of **AROQUET** is too strong or too weak, tell your doctor.

If you take more AROQUET XR than you should:

If you take more **AROQUET XR** than prescribed by your doctor you may feel sleepy and/or dizzy and experience abnormal heart beats. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison control centre.

If you stop taking AROQUET XR:

If you suddenly stop taking **AROQUET XR**, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

If you forget to take a dose of AROQUET XR:

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

AROQUET XR can cause side effects, although not everybody gets them. Should your general health worsen or if you experience any untoward effects while taking **AROQUET XR**, please consult your doctor, pharmacist or other healthcare professional for advice.

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If any of the following happens, stop taking / using **AROQUET XR** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,

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

Frequently occurring side effects:

- Constipation along with persistent abdominal pain
- Dizziness or a severe sense of feeling sleepy
- A fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may require **AROQUET XR** to be stopped and/or treatment to be given
- Thoughts of suicide and worsening of your depression especially when you are a young adult and have recently started taking **AROQUET XR**
- If you have thoughts of harming of killing yourself at any time. You may find it helpful to tell a relative or close friend that you are depresses and ask them to read this leaflet. You might ask them to tell you if they are worried about changes in your behaviour
- High levels of sugar in your blood, diabetes and triggering of underlying diabetes

- Increased heart beat
- Stiff, jerky movements of your face and body that you can't control

Less frequently occurring side effects:

- Uncontrollable movements, mainly of your face or tongue
- Fits (seizures)
- A long-lasting and painful erection (Priapism)
- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called “neuroleptic malignant syndrome”)

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dry mouth, vomiting (mainly in the elderly)
- Upset stomach (indigestion)
- Increases in the amount of liver enzymes measure in the blood
- Fainting
- Disturbance in speech and language
- Headache
- Decreases in the number of certain types of blood cells
- Rapid heartbeat
- Feeling like your heart is pounding, racing or has skipped beats
- Blurred vision
- Feeling hungrier

- Increased levels of sugar in the blood
- Changes in the amount of certain fats (triglycerides and total cholesterol)
- Decrease in “good cholesterol” (HDL-C)
- Putting on weight
- Abnormal dreams and nightmares
- Low blood pressure when standing up (orthostatic hypotension). This may make you feel dizzy or faint (may lead to falls)
- Increases in the amount of hormone prolactin in the blood
- Changes in the amount of thyroid hormones in your blood
- Feeling weak
- Feeling irritated
- Swelling of arms or legs
- Fever

Less frequent side effects:

- Difficulty swallowing
- Inflammation of the pancreas
- Bowel obstruction
- Increase of liver enzymes (AST) in the blood
- Unpleasant sensations in the legs (also called restless legs syndrome)
- Involuntary, repetitive body movements
- Decreases in the number of certain types of blood cells, decrease in the amount of red blood cells, decrease in platelets
- 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
- Diabetes
- Worsening of pre-existing diabetes
- 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” (HDLC), 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
- Stuffy nose
- 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
- Difficulty in passing urine
- Infection of the urinary tract
- Inappropriate secretion of a hormone that control the urine volume
- Sexual dysfunction
- Swelling of the breast and unexpected production of breast milk (galactorrhoea)
- Menstrual disorder
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens- Johnson syndrome)
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis)

- Increase blood creatine phosphokinase (a substance from the muscles).
- Sleep talking and sleep eating disorders
- Intestinal obstruction

Side effects reported with frequency unknown:

- Symptoms of withdrawal may occur in newborn babies of mothers that have used **AROQUET** during their pregnancy.
- 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).
- Serious, delayed hypersensitivity reaction with symptoms such as fever, skin rash, facial swelling, enlarged lymph nodes, organ involvement and an abnormal level of blood cells, eosinophilia, found in blood tests (Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)).
- Stroke

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **AROQUET XR** 5**0/150/200/300/400.**

5. How to store AROQUET XR

- Store at or below 25 °C.
- Store in original package until use.
- Do not use after the expiry date stated on the label and carton.
- Store all medicines out of reach of children.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AROQUET XR contains

- The active substance is quetiapine. **AROQUET XR** tablets contain 50 mg, 150 mg, 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine fumarate).
- The other ingredients are:

  Tablet core: hypromellose, lactose monohydrate**,** microcrystalline cellulose, povidone K30, sodium chloride, talc, magnesium stearate.

  Tablet coating: hypromellose, macrogol, titanium dioxide (E171). The 50 mg, 200 mg and 300 mg tablets also contain iron oxide yellow (E172) and the 50 mg tablets contain iron oxide red (E172).

What AROQUET XR looks like and contents of the pack

AROQUET XR 50 are peach colored, round shaped, biconvex film coated tablets, debossed with 'Q50' on one side and plain on other.

AROQUET XR 150 are white to off white, capsule shaped, biconvex, film coated tablets, debossed with 'AB2' on one side and plain on other side.

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AROQUET XR 200 are yellow coloured, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on other.

AROQUET XR 300 are light yellow coloured, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on other.

AROQUET XR 400 are white coloured, round shaped, biconvex, film coated tablets, debossed with 'I4' on one side and plain on other.

AROQUET XR 50 is packed in:

- PVC/PVdC-Alu blisters comprising of white opaque PVC film coated with PVdC and hard tampered aluminium with HSL coating on the bright side.
- Alu-Alu blisters comprising of cold formable, Alu-Alu, triple laminated foil and hard tampered aluminium foil with HSL coating on the bright side.

AROQUET XR 150 is packed in:

- PVC/PVdC-Alu blisters comprising of white opaque PVC film coated with PVdC and hard tampered aluminium with HSL coating on the bright side.
- Alu-Alu blisters comprising of cold formable, Alu-Alu, triple laminated foil and hard tampered aluminium foil with HSL coating on the bright side.
- HDPE bottle comprising of a white opaque HDPE container and a white opaque polypropylene child resistant closure with wad having an induction sealing liner.

AROQUET XR 200,300 and 400 are packed in:

- PVC/PVdC-Alu blisters comprising of white opaque PVC film coated with PVdC and hard tampered aluminium with HSL coating on the bright side.

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Pack sizes: 10,30,50,60,100 (Not all pack sizes will be marketed).

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park,

6 Coombe Place,

Rivonia,

Johannesburg,

South Africa

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6 April 2021

Registration number

AROQUET XR 50:48/2.6.5/0011

AROQUET XR 150:52/2.6.5/0998

AROQUET XR 200:48/2.6.5/0012

AROQUET XR 300:48/2.6.5/0013

AROQUET XR 400:48/2.6.5/0014

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