CLEAN PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

AROQUET 25/100/200/300

Film coated tablet

Quetiapine fumarate

Contains sugar (lactose)

Read all of this leaflet carefully before you are start using AROQUET

- 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** 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** is and what it is used for
2. What you need to know before you use **AROQUET**
3. How to use **AROQUET**
4. Possible side effects
5. How to store **AROQUET**
6. Contents of the pack and other information

1. What AROQUET is and what it is used for

AROQUET contains a substance called quetiapine. This belongs to a group of medicines called

antipsychotics.

AROQUET is indicated for:

1. The treatment of the manifestations of schizophrenia, a psychotic brain disorder where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
2. The treatment of manic episodes (where you may feel excited, elated, agitated, enthusiastic or hyperactive or have poor judgement including being aggressive or disruptive) associated with bipolar disorder

2. What you need to know before you use AROQUET

Do not use AROQUET if you

- are hypersensitive (allergic) to quetiapine or any of the components of **AROQUET** (see "WHAT **AROQUET** CONTAINS").
- are pregnant or breastfeeding.
- are a child or adolescent, as safety has not been demonstrated in persons under the age of 18.
- have advanced liver and kidney diseases.
- are taking any of the following medicines, such as some HIV medicines, antifungal medicines, erythromycin or clarithromycin (antibiotics) or nefazodone.

Warnings and precautions

Special care should be taken with **AROQUET** if you:

- 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

- have low blood pressure
- have had a stroke, especially if you are elderly
- have problems with your liver
- have ever had a fit (seizure)
- have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels regularly
- are an elderly person with dementia (loss of brain function). If you are, **AROQUET** should not be taken because the group of medicines that **AROQUET** belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia
- are an elderly person with Parkinson's disease/parkinsonism
- have a history of blood clots
- 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")
- 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
- have a history of alcohol or drug abuse.

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

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- 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).
- Changes in blood lipid levels (increases in triglycerides, LDL and total cholesterol and decreases in HDL cholesterol levels)
- Difficulty swallowing

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** 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.

- 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)
- Weight gain

Children and adolescents

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

Other medicines and AROQUET

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

Do not use **AROQUET** if you are taking any of the following medicines:

- Some medicines for HIV (such as indinavir, ritonavir, nelfinavir)
- Azole medicines (such as ketoconazole, fluconazole and itraconazole for fungal infections)
- Erythromycin or clarithromycin (for infections)
- Nefazodone (for depression)

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Tell your doctor if you are taking any of the following medicines:

- Epilepsy medicines (like phenytoin or carbamazepine)
- High blood pressure medicines (such as lisinopril, amlodipine or losartan)
- Barbiturates (for difficulty sleeping)
- 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 such as furosemide or hydrochlorothiazide) or certain antibiotics (medicines to treat infections such as erythromycin or clarithromycin)
- Medicines that can cause constipation (such as codeine or opioid type painkillers)
- Medicines (called “anti-cholinergics”) that affect the way nerve cells function in order to treat certain medical conditions (such as atropine or ipratropium or orphenadrine)

AROQUET with food, drink and alcohol

- Be careful how much alcohol you drink. This is because the combined effect of **AROQUET** and alcohol can make you sleepy
- Do not drink grapefruit juice while you are using **AROQUET**. It can affect the way **AROQUET** works.

Fertility, pregnancy & breastfeeding

Do not use **AROQUET** if you are pregnant or planning to become pregnant.

Do not use **AROQUET** if you are breastfeeding.

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Driving and using machines

AROQUET may impair your ability to drive and use machinery as it may cause somnolence (a very sleepy state). Do not drive, operate machinery, or do anything else that requires your attention until you know how **AROQUET** affects you.

AROQUET contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **AROQUET.**

3. How to use AROQUET

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

Always take **AROQUET** exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

Adults

For the treatment of schizophrenia: dose range of 300 to 450 mg/day

For the treatment of manic episodes associated with bipolar disorder: dose range of 400-800 mg/day

The prescribed dose is orally twice daily as 2 divided doses, with or without food.

You doctor will adjust your dose according to your response and tolerability to the treatment.

Elderly

AROQUET treatment will be with reduced initial and target dosages, and slower dosages changes may be required compared to younger adult patients.

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Kidney and liver diseases

If you have a kidney or liver disease, your **AROQUET** treatment will be with reduced initial and target dosages, and slower dosages changes may be required compared to younger adult patients.

Your doctor may perform certain urinary, blood tests or eye examinations to ensure the effectiveness and safe use of **AROQUET** prior and during your treatment.

Your doctor will tell you how long your treatment with **AROQUET** will last. If you have the impression that the effect of **AROQUET** is too strong or too weak, talk to your doctor or pharmacist.

If you take more AROQUET than you should

In the event of an accidental or intentional overdose, contact your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison control centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take a dose of AROQUET

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **AROQUET** at the next regularly scheduled time. Do not take a double or larger dose to make up for the forgotten individual doses.

If you stop using AROQUET

If you suddenly stop taking **AROQUET** 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.

4. Possible side effects

AROQUET can cause side effects, although not everybody gets them.

Not all side effects reported for **AROQUET** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **AROQUET**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of your face, lips, mouth, tongue, eyes or throat (angioedema).
- difficulty breathing, dizziness (severe hypersensitivity).

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

- Dizziness (may lead to falls), headache, dry mouth
- Feeling sleepy (this may go away with time - may lead to falls)
- Rapid heartbeat.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Feeling like your heart is pounding, racing or has skipped beats.

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- Feeling weak.
- Swelling of arms or legs.
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Increased levels of sugar in the blood.
- Blurred vision.
- Disturbance in speech and language.
- Thoughts of suicide and worsening of your depression.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fits or seizures
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Difficulty swallowing
- Uncontrollable movements, mainly of your face or tongue.
- 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.
- Fainting (may lead to falls).
- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).
- Yellowing of the skin and eyes (jaundice).
- Inflammation of the liver (hepatitis).

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- A long-lasting and painful erection (priapism).
- 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.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.
- Bowel obstruction.
- Severe rash, blisters, or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- 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.
- 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).
- Stroke

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

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Tell your doctor if you notice any of the following:

Frequent side effects:

- Discontinuation symptoms (symptoms which occur when you stop using **AROQUET**, 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.
- Putting on weight.
- Changes in the amount of certain fats (triglycerides and total cholesterol).
- Constipation, upset stomach (indigestion).
- Abnormal dreams and nightmares.
- Feeling more hungry.
- Feeling irritated.
- Fever.
- Changes in the amount of thyroid hormones in your blood.
- Decreases in the number of certain types of blood cells.
- Increases in the amount of liver enzymes measured in the 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

Less frequent side effects:

- Unpleasant sensations in the legs (also called restless legs syndrome).
- Sexual dysfunction

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- Diabetes.
- Stuffy nose.
- Decrease in the amount of red blood cells.
- Decrease in the amount of sodium in the blood.
- Worsening of pre-existing diabetes
- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- Inflammation of the pancreas.
- 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.
- Increased blood creatine phosphokinase (a substance from the muscles).
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis).

Side effects reported with unknown frequency:

- Symptoms of withdrawal may occur in newborn babies of mothers that have used **AROQUET** during their pregnancy.

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

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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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **AROQUET**.

5. How to store AROQUET

- Store at or below 25 ºC, protected from light and moisture.
- Do not remove the tablets from the container until required for use.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AROQUET contains

The active substance is:

AROQUET 25 mg tablet: Each tablet contains quetiapine fumarate 28,78 mg equivalent to 25 mg of quetiapine.

AROQUET 100 mg tablet: Each tablet contains quetiapine fumarate 115,12 mg equivalent to 100 mg of quetiapine.

AROQUET 200 mg tablet: Each tablet contains quetiapine fumarate 230,24 mg equivalent to 200 mg of quetiapine.

AROQUET 300 mg tablet: Each tablet contains quetiapine fumarate 345,36 mg equivalent to

300 mg of quetiapine.

The other ingredients are:

Tablet core: lactose monohydrate, sodium starch glycolate (Type A), dibasic calcium hydrogen phosphate dihydrate, povidone K30, cellulose Microcrystalline (PH102), magnesium stearate

Tablet coating:

AROQUET 25: Opadry Pink

AROQUET 100: Opadry Yellow

AROQUET 200/300: Hypromellose E-5, Macrogol 400, Titanium Dioxide

What AROQUET looks like and contents of the pack

AROQUET 25: Pink coloured, round shaped, biconvex, film coated tablets, plain on both sides.

AROQUET 100: Yellow coloured, round shaped, biconvex, film coated tablets, plain on both sides.

AROQUET 200: White to off white, round shaped, biconvex, film coated tablets, plain on both sides.

AROQUET 300: White to off white, capsule shaped, biconvex, film coated tablets, debossed with “300” on one side and plain on other side.

AROQUET 25/100/200/300 tablets are packed into clear transparent / silver aluminium blisters strips, containing 10/12/15 tablets each.

AROQUET 25: Pack sizes of 100 tablets

AROQUET 100: Pack sizes of 90 tablets

AROQUET 200: Pack sizes of 60 tablets

AROQUET 300: Pack sizes of 60 tablets

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HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park, Building 2

6 Coombe Place

Rivonia

Johannesburg

South Africa

This leaflet was last revised in

To be confirmed

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