

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

SEROQUEL® 25 (Quetiapine 25 mg) (Tablet)

SEROQUEL® 100 (Quetiapine 100 mg) (Tablet)

SEROQUEL® 200 (Quetiapine 200 mg) (Tablet)

SEROQUEL® 300 (Quetiapine 300 mg) (Tablet)

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SEROQUEL 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.

1. WHAT SEROQUEL CONTAINS:

- SEROQUEL 25: The active substance is quetiapine fumarate 28,78 mg that is equivalent to 25 mg of quetiapine free base.
- SEROQUEL 100: The active substance is quetiapine fumarate 115,13 mg that is equivalent to 100 mg of quetiapine free base.
- SEROQUEL 200: The active substance is quetiapine fumarate 230,26 mg that is equivalent to 200 mg of quetiapine free base.
- SEROQUEL 300: The active substance is quetiapine fumarate 345,39 mg that is equivalent to 300 mg of quetiapine free base.

Contains sugar (lactose monohydrate).

The other ingredients are calcium hydrogen phosphate, ferric oxide, lactose monohydrate, macrogol, magnesium stearate, methylhydroxypropylcellulose, microcrystalline cellulose, povidone, sodium starch glycollate, and titanium dioxide.

2. WHAT SEROQUEL IS USED FOR:

SEROQUEL belongs to a group of medicines called antipsychotics. Antipsychotics improve the symptoms of certain types of mental illnesses. SEROQUEL is used to treat hallucinations (for example unexplained voices), strange and frightening thoughts, changes in your behaviour, feeling alone and confused.

SEROQUEL is also used to treat people with an illness that affects their mood whereby they feel 'high' or excited. People with this condition may find that they need to sleep less than usual, are more talkative and have racing thoughts or ideas. They may also feel unusually irritable.

3. BEFORE YOU TAKE SEROQUEL:

Do not take SEROQUEL:

- If you are allergic to quetiapine fumarate or any other ingredients of SEROQUEL.
- If you are a child or teenager.
- If you have severe kidney or liver problems.
- If you are an elderly patient with dementia and behavioural disturbances.

Take special care with SEROQUEL:

Before taking SEROQUEL tell your doctor, pharmacist or other health care professional:

- If you have any health problems.
- If you have any heart problems and/or low blood pressure or have had a stroke.
- If you suffer from diabetes mellitus or have a family history of diabetes mellitus, your glucose levels may worsen or you may develop signs of increased glucose levels (such as frequent urination, thirst and increased appetite). Your glucose levels should therefore be monitored more closely and regularly with more frequent consultation with your doctor.
- If you or a family member have a history of any problems with the way your heart beats or have a history of heart disease or heart problems or if you are taking any medicines that may have an impact on the way your heart beats.
- If you have ever had a seizure (fit).
- If you have any kidney or liver problems – please refer to the “Dosage and directions of use” in the package insert.
- If you know that you had a low white blood cell count in the past which may or may not have been caused by other medicines.
- If you have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called “sleep apnea”) and are taking medicines that slow down the normal activity of the brain (“depressants”).
- If 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 “anticholinergics”) that affect the way nerve cells function in order to treat certain medical conditions.
- If you have a history of alcohol or drug abuse.

While you are taking SEROQUEL tell your doctor, pharmacist or other health care professional:

- If you feel “light-headed” and think you have low blood pressure.
- If you experience movements of your facial muscles and tongue, and your hand and leg muscles, without your control (tardive dyskinesia).
- If you feel you have a fever, feel confused or drowsy, muscle stiffness or changes in your blood pressure or heartbeats (neuroleptic malignant syndrome).
- 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 SEROQUEL to be stopped and/or treatment to be given.
- If you have 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.
- If you have pancreatitis (inflammation of the pancreas). You may have had factors which are known to be associated with pancreatitis such as increased triglyceride levels (a fatty substance in the blood), gallstones, and alcohol consumption.
- If you have cardiomyopathy (weakening of the heart muscle) and myocarditis (inflammation of the heart).
- If you have thoughts of suicide and worsening of your depression or other mental illnesses. If you are depressed and/or have other mental illnesses 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.
- 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 or have other mental illnesses, and ask them to read this leaflet. You might ask them to tell you if

they think your depression or mental illness is getting worse, or if they are worried about changes in your behaviour.

Taking SEROQUEL with food and drink:

If you drink alcohol, please mention this to your doctor before you start to take SEROQUEL.

Pregnancy and breast feeding:

Before taking SEROQUEL, tell your doctor if you are pregnant, trying to become pregnant or are breast feeding.

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

<p>If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking SEROQUEL</p>

Driving and using machinery:

Your tablets may make you feel sleepy. This may disappear while you continue taking your tablets. Even so, you should not drive or use machinery until you know how these tablets affect you.

Taking other medicines with SEROQUEL:

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

In particular, tell your doctor if you are taking, or are about to stop taking medicines for:

- Anxiety, depression (such as centrally acting drugs, alcohol or an antipsychotic drug called thioridazine).
 - Epilepsy (such as phenytoin, carbamazepine or sodium valproate).
 - Human Immunodeficiency Virus (HIV) (such as protease inhibitors).
 - Sleeplessness (such as barbiturates).
 - Tuberculosis (such as rifampicin).
 - Fungal infections (such as ketoconazole).
 - Other infections (such as macrolide antibiotics).
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- If you are taking medicines that have an impact on the way and how slow your heart beats, those that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (drugs to treat infections).
 - Medicines that can cause constipation.
 - If you are taking medicines (such as anticholinergics) that affect the way nerve cells function in order to treat certain medical conditions.
 - If you are having a urine screen, taking SEROQUEL may cause positive results for methadone or certain drugs 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.

4. HOW TO TAKE SEROQUEL:

- Always take SEROQUEL exactly as your doctor has instructed you.
- You should check with your doctor or pharmacist if you are unsure.
- Your doctor may adjust your daily dose of SEROQUEL between 150 mg and 800 mg depending on your individual treatment and needs.

- If you have the impression that the effect of SEROQUEL is too strong or too weak, talk to your doctor or pharmacist.
- Seroquel is to be taken twice a day either with or without food.
- Swallow your tablets whole with a drink of water.
- SEROQUEL tablets come in different sizes, and each size is a different colour. Therefore don't be surprised if the colour of your tablets differs from time to time.
- Do not share your medicines prescribed for you with any other person.
- Your doctor will tell you how long your treatment with SEROQUEL will last. Do not stop taking your tablets even if you are feeling better, unless your doctor tells you.

If you take more SEROQUEL than you should:

If you take more than the recommended number of tablets, you are likely to feel drowsy, sleepy, rapid heartbeat and light-headed (low blood pressure).

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

If you forget to take SEROQUEL:

If you miss a dose, take the dose as soon as you remember, but do not take your next dose at the same time. Then go on as before.

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

5. POSSIBLE SIDE EFFECTS:

SEROQUEL can have side effects.

Not all side effects reported for SEROQUEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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.
- Reduced consciousness.
- Fits (seizures).
- Priapism (long-lasting and painful erection).

Tell your doctor if any of the following side effects bothers you:

Frequent side effects:

- Dizziness (may lead to falls).
- Feeling sleepy (this may go away whilst you continue taking your tablets).
- Headache (this may or may not be caused by taking SEROQUEL).
- Rapid heart beat.
- Feeling like your heart is pounding, racing or has skipped beats.
- Dry mouth.
- Constipation.
- Indigestion.
- Feeling weak.
- Swelling of arms and legs.
- Weight gain, mainly during the first weeks of treatment.

- Fainting.
- Anxiety (this may or may not be caused by taking SEROQUEL).
- Stuffy nose.
- Low blood pressure in standing position, which may result in dizziness or feeling faint.
- Urinary tract infection (bladder infection) (this may or may not be caused by taking SEROQUEL).
- Fever
- Discontinuation symptoms (i.e., symptoms which occur upon stopping SEROQUEL) include vomiting, dizziness, nausea, headache, diarrhea, insomnia, and irritability. Gradual withdrawal over a period of at least one to 2 weeks is advisable).
- You may have abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
- Blurred vision.
- Abnormal dreams and nightmares.
- Irritability.
- Feeling more hungry.
- Disturbance in speech and language.
- Shortness of breath.
- Vomiting (mainly in the elderly)

Less frequent side effects:

- Allergic reaction that may include itchy rash, weals and swelling of the skin.
- Fits (seizures).
- Fever.
- Restless legs (unpleasant sensations in the legs).

- Difficulty swallowing.
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia)
- 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.
- Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called “neuroleptic malignant syndrome”)
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Very marked drowsiness.
- Muscle stiffness.
- Changes in blood pressure or heartbeats.
- Reduced consciousness.
- Priapism (long-lasting and painful erection).
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia)
- 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.
- Inflammation of the liver with or without jaundice (a yellowish discoloration of the skin/palms or whites of your eyes).
- Anaphylaxis (severe form of allergic reaction; may include severe difficulty breathing and shock).
- Symptoms of withdrawal may occur in newborn babies of mothers that have used SEROQUEL during their pregnancy

The following side effects can also occur with SEROQUEL, and they are seen when a blood test is taken:

- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of SEROQUEL.
- Decrease in the amount of red blood cells. These are the cells that transport oxygen throughout the body.
- Increase in the amount of eosinophils. These are a “Eosinophilia”, an increase in one type of white blood cells which is sometimes seen in allergic reactions.
- “Thrombocytopenia”, a decrease in platelets, which are cells that help you stop bleeding if you get a cut.
- Increase in the amount of liver enzymes. These changes will normally disappear when continuing the treatment of SEROQUEL.
- Increase in the amount of fatty substances (lipid levels, such as triglycerides and cholesterol) in the blood.
- Increase in the amount of ‘creatinine phosphokinase’, a substance in the muscles.
- Increase in the amount of sugar (glucose) in the blood.
- Increase in the amount of the hormone prolactin in the blood. This may lead to:
 - Men and women to have swelling of breasts and unexpectedly produce breast milk.
 - Women to have no monthly period or irregular periods.
- Changes in the amount of thyroid hormones in your blood. These changes usually do not affect how you feel.

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

6. STORING AND DISPOSING OF SEROQUEL:

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not use SEROQUEL after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF SEROQUEL:

SEROQUEL tablets are packed into PVC aluminium foil blister strips that are placed into cartons.

- SEROQUEL 25: Packs of 6 or 100 tablets.
- SEROQUEL 100: Packs of 60; 90 or 100 tablets.
- SEROQUEL 200: Packs of 60; 90 or 100 tablets.
- SEROQUEL 300: Packs of 60; 90 or 100 tablets.

8. IDENTIFICATION OF SEROQUEL:

- SEROQUEL 25: Peach, round, bi-convex, film-coated tablet intagliated with SEROQUEL 25.
- SEROQUEL 100: Yellow, round, bi-convex, film-coated tablet intagliated with SEROQUEL 100.
- SEROQUEL 200: White, round, bi-convex, film-coated tablet intagliated with SEROQUEL 200.
- SEROQUEL 300: White, capsule-shaped, film-coated tablet intagliated with SEROQUEL on one side and 300 on the other.

9. REGISTRATION NUMBER:

- SEROQUEL 25: 32/2.6.5/0589
- SEROQUEL 100: 32/2.6.5/0590
- SEROQUEL 200: 32/2.6.5/0591
- SEROQUEL 300: 36/2.6.5/0070

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AstraZeneca Pharmaceuticals (Pty) Limited
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17 Georgian Crescent West,
Bryanston, Johannesburg
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11. DATE OF PUBLICATION:

Date on registration certificate:

13 June 2008

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CPIL: 21 September 2016

Inclusion of Namibia + Botswana registration details (01-03-2011)

Seroquel 25	Seroquel 100	Seroquel 200	Seroquel 300
NAMIBIA: NS3	NAMIBIA: NS3	NAMIBIA: NS3	NAMIBIA: NS3
Reg. No.:	Reg. No.:	Reg. No.:	Reg. No.:
10/2.6.5/0586	10/2.6.5/0587	10/2.6.5/0588	10/2.6.5/0580

Seroquel 25	Seroquel 100	Seroquel 200	Seroquel 300
BOTSWANA: S2	BOTSWANA: S2	BOTSWANA: S2	BOTSWANA: S2
Reg. No.: BOT	Reg. No.: BOT	Reg. No.: BOT	Reg. No.: BOT
1101819	1101820	1101821	1101947