PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

DOPAQUEL 25, 25 mg, film-coated tablets

DOPAQUEL 100, 100 mg, film-coated tablets

DOPAQUEL 200, 200 mg, film-coated tablets

DOPAQUEL 300, 300 mg, film-coated tablets

Quetiapine fumarate

Contains sugar: Lactose monohydrate

DOPAQUEL 25 contains sugar (19,821 mg lactose monohydrate per tablet).

DOPAQUEL 100 contains sugar (79,285 mg lactose monohydrate per tablet).

DOPAQUEL 200 contains sugar (158,569 mg lactose monohydrate per tablet).

DOPAQUEL 300 contains sugar (237,854 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking DOPAQUEL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DOPAQUEL 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 DOPAQUEL is and what it is used for

2. What you need to know before you take DOPAQUEL

3. How to take DOPAQUEL

4. Possible side effects

5. How to store DOPAQUEL

6. Contents of the pack and other information

1. What DOPAQUEL is and what it is used for

DOPAQUEL belongs to a group of medicines called antipsychotics.

DOPAQUEL is used to treat the following conditions:

- Schizophrenia (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)
- Mania in patients with bipolar disorder (where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive).

2. What you need to know before you take DOPAQUEL

Do not take DOPAQUEL:

- if you are hypersensitive (allergic) to quetiapine or any of the other ingredients of DOPAQUEL (listed in section 6)
- if you are pregnant or breastfeeding
- if you have severe kidney or liver problems
- if you are a child or an adolescent below the age of 18 years
- if you are using any of the following medicines:

- protease inhibitors (for HIV infection)
- azole medicines (for fungal infections)
- erythromycin or clarithromycin (for infections)
- nefazodone (for depression).

- If you are an elderly person with dementia (memory loss).

Warnings and precautions

Take special care with DOPAQUEL:

Before you take DOPAQUEL, tell your doctor, pharmacist or other health care professional:

- If you have diabetes mellitus or have a risk of getting diabetes (e.g. obesity, family history of diabetes), as DOPAQUEL may increase blood sugar levels further and worsen blood sugar control. Your doctor may check your blood sugar levels regularly while you are taking DOPAQUEL.

  Symptoms of high levels of blood sugar include drinking excessive amounts of water, having to urinate frequently, eating excessively and weakness
- If you, or someone in your family, have or have had any heart problems, such as heart rhythm problems (e.g. QT prolongation), 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. Also tell your doctor if you have low blood potassium or low blood magnesium
- If you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- 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 had a stroke, especially if you are elderly
- If you are an elderly person with dementia (loss of brain function).

  If you are, DOPAQUEL should not be taken because the group of medicines that DOPAQUEL belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- If you are an elderly person with Parkinson's disease/parkinsonism
- If you are at risk for developing a breathing condition called aspiration pneumonia (where food, saliva, liquids or vomit is breathed into the lungs or airways leading to the lungs), since DOPAQUEL may cause problems with swallowing
- If you have low blood pressure
- If you have known cardiovascular disease (disease of the heart and blood vessels), cerebrovascular disease (disease of the brain and its blood vessels) or other conditions that may lead to low blood pressure, as DOPAQUEL may induce orthostatic hypotension (low blood pressure when you stand up), associated with symptoms of dizziness, increase in heart rate and sometimes fainting, especially if you are elderly
- 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 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.

- If you have a history of alcohol or drug abuse
- If you have any kidney or liver problems
- If you have a history of seizures (fits)
- If you have depression or other conditions that are treated with antidepressants. The use of these medicines together with DOPAQUEL can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and DOPAQUEL").

Tell your doctor immediately or go to the nearest hospital if you experience any of the following after taking DOPAQUEL:

- A combination of fever, severe muscle stiffness, very marked drowsiness, marked increase in blood pressure or heartbeats, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.
- Dizziness, lightheadedness, and fainting when you get up from a lying position. This is more common when you first start taking DOPAQUEL, and can increase the risk of accidental injury (fall) if you are elderly
- Restlessness and a need to move or an inability to sit or stand still (akathisia)
- Uncontrollable movements, mainly of your face or tongue (tardive dyskinesia)
- A severe sense of feeling sleepy. This is more common during the first two weeks of treatment
- A long-lasting and painful erection (Priapism)
- Fits (seizures)
- Have a fast and irregular heartbeat, even when you are at rest, palpitations, breathing

problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, refer you to a cardiologist immediately.

Tell your doctor as soon as possible if you have:

- A fever, flu-like symptoms, sore throat, weakness, or any other infection, as this could be a result of a very low white blood cell count, which may require DOPAQUEL 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.

Pancreatitis (inflammation of the pancreas) has been reported in some patients. Many of these patients also 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.

Cardiomyopathy (weakening of the heart muscle) and myocarditis (inflammation of the heart) have been reported in some patients.

Thoughts of suicide and worsening of your depression

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. These thoughts may also be increased if you suddenly stop taking your medication.

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

Severe cutaneous adverse reactions (SCARs)

Severe skin related adverse reactions which can be life threatening or fatal have been reported 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)
- Acute Generalized Exanthematous Pustilosis (AGEP), small blisters filled with pus
- Erythema Multiforme (EM), skin rash with itchy-red irregular spots

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

Weight gain

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

Cholesterol

DOPAQUEL may increase your cholesterol in the blood.

Your doctor might monitor your cholesterol levels while you are taking DOPAQUEL.

Effects on urine medicine screens

If you are having a urine medicine screen, taking DOPAQUEL may cause positive results for methadone or tricyclic antidepressants (medicines used for depression) when some test methods are used, even though you may not be taking methadone or tricyclic antidepressants. If this happens, a more specific test can be performed.

Children and adolescents

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

Other medicines and DOPAQUEL

Always tell your healthcare professional if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Do not take DOPAQUEL if you are taking any of the following medicines:

- Some medicines for Human Immunodefienciency Virus (HIV) (protease inhibitors)
- Azole medicines, such as ketoconazole (for fungal infections)
- Erythromycin or clarithromycin (for infections)
- Nefazodone (for depression).

Tell your doctor if you are taking any of the following 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 (medicines to treat infections).
- Medicines that can cause constipation
- Medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions
- Levodopa (for Parkinson's disease)

- Medicines for anxiety or depression (such as centrally acting medicines and alcohol)
- Medicines used for high blood pressure
- Rifampicin (for tuberculosis)
- Barbiturates (for difficulty in sleeping)
- Thioridazine (another anti-psychotic medicine)
- Lithium (medicine used to treat some types of depression)
- Imipramine, fluoxetine (medicines used to treat depression)
- Anti-epileptic medicines (such as carbamazepine, phenytoin or sodium valproate)
- Anti-depressants. These medicines may interact with DOPAQUEL and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C (serotonin syndrome). Contact your doctor when experiencing such symptoms.

Before you stop taking any of your medicines, speak to your doctor first.

DOPAQUEL with food, drink and alcohol

- DOPAQUEL can be taken with or without food.
- Be careful how much alcohol you drink. This is because the combined effect of DOPAQUEL and alcohol may make you sleepy.
- Do not drink grapefruit juice while taking DOPAQUEL. It can affect the way DOPAQUEL works.

Pregnancy and breastfeeding

Do not take DOPAQUEL during pregnancy and while breastfeeding your baby.

Symptoms of withdrawal have occurred in newborn babies of mothers that have used quetiapine, as in DOPAQUEL, during their pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DOPAQUEL.

Driving and using machines

DOPAQUEL may make you feel drowsy/sleepy. Do not drive or use any machines or tools until you know how the tablets affect you.

DOPAQUEL contains lactose monohydrate

DOPAQUEL contains lactose which is a type of sugar. If you have an intolerance to some sugars, please speak to your doctor or pharmacist before taking DOPAQUEL.

3. How to take DOPAQUEL

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

Always take DOPAQUEL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of DOPAQUEL is too strong or too weak, tell your doctor or pharmacist.

Your doctor will decide on your starting dose and may gradually increase it. After this the total daily dose will usually be between 150 mg and 800 mg each day, but this depends on your illness and is determined by your doctor.

- The usual dose is taken twice a day by mouth (orally)
- You can take your tablets with or without food.

Elderly

If you are elderly, your doctor will start DOPAQUEL therapy at a lower dose and then gradually increase it.

Your maintenance dose (daily dose) is also likely to be lower than that in younger patients.

Kidney and liver impairment

Your dose should be started on DOPAQUEL 25 mg/day. Your healthcare professional will adjust the dose if needed.

If you take more DOPAQUEL than you should

If you have exceeded your prescribed dose of DOPAQUEL, you may experience symptoms of drowsiness, feeling sleepy, increased rate of heart beat and low blood pressure.

Taking too much DOPAQUEL may also cause convulsions (seizures), muscle pain, decreased urine, confusion, agitation, inhibition of breathing, coma and death.

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

If you forget to take DOPAQUEL

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 a forgotten tablet.

If you stop taking DOPAQUEL

If you suddenly stop taking DOPAQUEL, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhoea, dizziness, being sick (vomiting), or irritability.

Your disease symptoms may return and movement disorders such as restlessness and a need to move (akathisia), muscle contractions causing repetitive or twisting movements (dystonia) and uncontrollable muscle movements (dyskinesias) may occur.

Your doctor may suggest you reduce the dose gradually over a period of at least one to two weeks before stopping treatment.

4. Possible side effects

DOPAQUEL can have side effects.

Not all side effects reported for DOPAQUEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOPAQUEL, please consult your health care provider for advice.

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

Frequency not known:

- Severe, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).

Frequent side effects:

- Thoughts of suicide and worsening of your depression.

Less frequent side effects

- Hypersensitivity (allergic reactions including rapid swelling around the mouth or throat or swelling of all layers of the skin), severe allergic reactions (difficulty in breathing,

dizziness and collapse), itching and rash

- Seizures (fits)
- Yellowing of the skin and eyes (jaundice), inflammation of the liver (hepatitis)
- Blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing
- Uncontrollable movements, mainly of the face and tongue (tardive dyskinesia)
- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat (a disorder called "neuroleptic malignant syndrome")
- A long-lasting and painful erection (priapism)
- A severe blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).

These are all very serious side effects. 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:

Frequent side effects:

- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls)
- A severe sense of feeling sleepy (may lead to falls)
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.

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

Tell your doctor as soon as possible if you notice any of the following:

Less frequent side effects:

- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis
- Constipation, nausea, vomiting, diarrhoea, crampy abdominal pain. These may be symptoms of bowel obstruction.

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

- A decrease in the number of white blood cells
- An abnormally high number of eosinophils (a type of white blood cell)
- Increases 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.
- Increased levels of sugar in the blood
- Abnormal dreams and nightmares, feeling irritable
- Headache, dizziness (may lead to falls), feeling anxious, problems with speech
- Feeling sleepy (this may go away whilst you continue taking your tablets)
- Blurred vision
- Rapid heartbeat, feeling like your heart is pounding, racing or has skipped beats

- Shortness of breath
- Dry mouth, constipation, upset stomach (indigestion), vomiting
- Irritability
- Fever
- Feeling more hungry
- Putting on weight
- Feeling weak, swelling of arms or legs, discontinuation symptoms (symptoms which occur when you stop taking DOPAQUEL **–** see **"If you stop taking DOPAQUEL"**).

Less frequent side effects

- Decreases in the number of certain types of blood cells, anaemia (a decrease in red blood cells causing tiredness, weakness, pale skin)
- Bleeding or bruising more easily than normal
- Increased blood sugar, diabetes
- Underactive thyroid, inappropriate secretion of a hormone that controls urine volume
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema)
- Walking, talking or eating while you are asleep
- Unpleasant sensations in the legs (called restless legs syndrome)
- Fainting (may lead to falls)
- Ear pain
- Change in electrical activity of the heart seen on ECG (QT prolongation), a slower than normal heart rate, chest pain
- Stuffy nose
- Confusion

- Diarrhoea, abdominal pain, difficulty swallowing, inflammation of the pancreas
- Muscle pain, breakdown of muscle fibres and pain in muscles (rhabdomyolysis), back pain
- Infection of your urinary tract, difficulty in passing urine
- Unexpected production of breast milk (galactorrhoea), swelling of breasts, sexual dysfunction, menstrual disorder
- Decrease in the amount of sodium in the blood
- A condition (called "metabolic syndrome") where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in "good cholesterol" (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar
- Fever, decreased body temperature (hypothermia).

Frequency not known:

- Dry eyes, changes in the lenses of the eyes
- Stroke
- Combination of widespread rash, high body temperature, blood abnormalities (liver enzyme elevations, increase in a type of white blood cells sometimes seen in allergic reactions) and enlarged lymph nodes (a condition called "drug reaction with eosinophilia and systemic symptoms") may occur.
- Rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid called as Acute Generalized Exanthematous Pustulosis (AGEP))
- A severe form of skin rash with itchy pink-red irregular spots (a condition known as

Erythema multiforme (EM)) may occur

- Inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps
- Disorder of the heart muscle (cardiomyopathy)
- Inflammation of the heart muscle (myocarditis)
- Symptoms of withdrawal may occur in newborn babies of mothers that have used DOPAQUEL during their pregnancy.

Some side effects are only seen when a blood test is taken. These include changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, changes in the amount of thyroid hormones in the blood, increased liver enzymes, decreases in the number of certain types of blood cells, increased blood creatinine phosphokinase (a substance in the muscles), decrease in the amount of sodium in the blood, increases in the amount of the hormone prolactin in the blood and decreases in haemoglobin (a protein found in red blood cells that carries oxygen around your body).

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

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

Reporting of side effects

If you get side effects, talk to your doctor or 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 DOPAQUEL.

5. How to store DOPAQUEL

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

Keep the container tightly closed.

Keep tablets in the original container.

Do not store in bathrooms or close to sources of heat.

Do not use after the expiry date stated on the label, carton, blister pack or bottle.

Return all unused and expired medicine to your pharmacist.

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

Store all medicines out of reach of children.

6. Contents of the pack and other information

What DOPAQUEL contains:

The active substance is quetiapine.

DOPAQUEL film-coated tablets contain quetiapine fumarate equivalent to 25 mg, 100 mg, 200 mg or 300 mg of quetiapine.

The other ingredients in DOPAQUEL are: colloidal silicon dioxide, dibasic calcium phosphate dihydrate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate. The 25, 200 and 300 mg tablets also contain Opadry® white (hypromellose, macrogol and titanium dioxide). The 100 mg tablets also contain Opadry® yellow (hypromellose, iron oxide yellow, macrogol and titanium dioxide).

What DOPAQUEL looks like and contents of the pack

DOPAQUEL 25: White, round, biconvex, film-coated tablets debossed with 'R' on one

side and '1' on the other side.

DOPAQUEL 100: Yellow, round, biconvex, film-coated tablets debossed with 'R' on one side and '3' on the other side.

DOPAQUEL 200: White, round, biconvex, film-coated tablets debossed with 'R' on one side and '5' on the other side.

DOPAQUEL 300: White, modified capsule shaped, biconvex, film-coated tablets debossed with 'R' on one side and '6' on the other side.

DOPAQUEL 25: 30, 60, 100 or 500 film-coated tablets in white HDPE containers. Transparent PVC/PVdC/paper backed Alu blister strips containing 7, 10, 14, 28 or 30 tablets.

DOPAQUEL 100: 30, 60, 90, 100 or 500 film-coated tablets in white HDPE containers. Transparent PVC/PVdC/paper backed Alu blister strips containing 7, 10, 14, 28 or 30 tablets.

DOPAQUEL 200: 30, 60, 100 or 500 film-coated tablets in white HDPE containers. Transparent PVC/PVdC/paper backed Alu blister strips containing 7, 10, 14, 28 or 30 tablets.

DOPAQUEL 300: 30, 60, 100 or 500 film-coated tablets in white HDPE containers. Transparent PVC/PVdC/paper backed Alu blister strips containing 7, 10, 14, 28 or 30 tablets.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road

Morningside

Sandton

2057

South Africa

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DOPAQUEL 300: 43/2.6.5/0432

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100