

Patient Information Leaflet – proposed clean**SCHEDULING STATUS:** S5**Psyquet® 100 (film-coated tablets)****Psyquet® 200 (film-coated tablets)****Psyquet® 300 (film-coated tablets)**

quetiapine fumarate

Each PSYQUET 100 mg film coated tablet contains sugar (22,82 mg lactose monohydrate).

Each PSYQUET 200 mg film coated tablet contains sugar (45,72 mg lactose monohydrate).

Each PSYQUET 300 mg film coated tablet contains sugar (68,58 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking PSYQUET

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

1. What PSYQUET is and what it is used for**PSYQUET tablets are indicated for:**

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- The treatment of the manifestations of schizophrenia, a psychotic brain disorder.
- The treatment of manic episodes associated with bipolar disorders.

2. What you need to know before you take PSYQUET

Do not take PSYQUET:

- If you are hypersensitive (allergic) to quetiapine or any of the other ingredients of PSYQUET (see “What PSYQUET contains”).
- If you are pregnant or breastfeeding (see “Pregnancy and Breastfeeding”).
- If you are a child or adolescent, below the age of 18 years.
- If you have severe liver and kidney diseases.
- If you are an elderly patient with a condition called dementia (loss of memory, language skills and thought processes).
- Certain medicines may enhance the effects of PSYQUET and therefore increase the risk of side effects. These medicines include erythromycin, fluconazole, ketoconazole (used for treatment of certain infections) and HIV-protease inhibitors (medicines used for HIV infections).

Warnings and precautions

Take special care with PSYQUET:

- PSYQUET is not recommended for use in children and adolescents below 18 years of age.
- If you have ever thought of killing yourself or think about killing yourself.
- If you have symptoms e.g., continuous spasms and muscle contractions, slowness of movement, tremor, or irregular, jerky movements.
- If you have a condition which cause your bladder not to empty completely, have an enlarged prostate, any internal blockage of the bowel, or if you have glaucoma, a condition where the pressure in your eyes is increased.
- If you or anybody in your family have a heart rhythm disorder that causes the heart to beat irregularly.

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- If you have diabetes mellitus or a condition where your blood glucose is high.
- If you suffer from orthostatic hypotension, a condition where your blood pressure drops when you stand up from a sitting or lying position.
- If you have a condition called cardiomyopathy, a disease of the heart muscle that makes it harder for your heart to pump blood to the rest of your body; or if you have myocarditis, a condition where there is inflammation in the heart muscle.
- If you experience involuntary movements of the face and jaw.
- If you experience sleepiness and drowsiness.
- If you suffer from seizures.
- If you have a condition called neuroleptic malignant syndrome (NMS) a rare, but life-threatening, idiosyncratic reaction to neuroleptic medications that is characterised by fever, muscular rigidity, altered mental status, and autonomic dysfunction.
- If you have a condition which causes the white blood cells in your body to decrease, you may get more infections than usual.
- If your doctor has decided to stop your treatment, you should be tapered off slowly and not stop immediately to avoid withdrawal symptoms, including nausea, inability to sleep, headaches, diarrhoea, vomiting, dizziness, and irritability.
- If you have a history of alcohol and drug abuse.
- If you suffer from sleep apnoea, a condition where breathing repeatedly stops and starts or if you feel tired after a night's sleep, snore loudly or are overweight.
- If you use medicine called carbamazepine or phenytoin, used to treat epilepsy.
- Your weight may be increased.
- If you are more thirsty than normal, urinating more than usual, eating more than usual or feeling weak, as it may mean the glucose level in your blood is higher than usual.
- If the cholesterol levels in your blood increase.
- If you are elderly and suffer from hallucinations (usually visual), delusions, and delusional misidentifications.

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- If you are elderly and suffer from a condition called Parkinsonism, which causes slowness of movement, stiffness in your body, shakiness, and imbalance.
- If you struggle to swallow.
- If you suffer from constipation.
- If you ever have blood clots before.
- If you experience upper abdominal pain, especially if it is worse after eating, fever, rapid pulse, nausea, vomiting, or tenderness when touching the abdomen.
- If you are taking medicine called divalproex or lithium, used to treat depression.

Other medicines and PSYQUET

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

The following medicines may cause an interaction when used in combination with PSYQUET:

- Some centrally acting medicines used to treat hypertension.
- Alcohol.
- Medicines that can have an influence on the heart rate.
- Levodopa, used to treat Parkinson-like symptoms (e.g., shakiness, stiffness, difficulty moving).
- Anti-cholinergic medicines, used to treat overactive bladder.
- HIV protease inhibitors, used to treat HIV-infection.
- Erythromycin, used in the treatment of bacterial infection.
- Fluconazole, itraconazole and ketoconazole, used to treat fungal infections.
- Lithium, used to treat depression.
- Risperidone, haloperidol or thioridazine, used to treat schizophrenia, depression or behaviour problems.

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- Rifampicin, used to treat TB.
- Risperidone, haloperidol or thioridazine, used to treat schizophrenia, depression or behaviour problems.
- Methadone, used to treat heroin addiction.
- Tricyclic antidepressants, used in treatment of depression.

PSYQUET with food and drink

The tablets may be taken with or without food and a glass of water.

Pregnancy, breastfeeding and fertility

You should not take PSYQUET when you are pregnant.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines

Caution should be taken when driving or operating any machinery when taking PSYQUET as it may cause drowsiness.

PSYQUET contains lactose monohydrate

PSYQUET contains lactose monohydrate. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take PSYQUET.

PSYQUET contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take PSYQUET

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Always take PSYQUET exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

The usual dose is one tablet to be taken by mouth twice a day with or without food.

Your doctor will tell you how long your treatment with PSYQUET will last. Do not stop treatment earlier than what the doctor has instructed you.

If you have the impression that the effect of PSYQUET is too strong or too weak, talk to your doctor or pharmacist.

If you take more PSYQUET than you should

In the event of an over dosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center 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 PSYQUET

If you forget to take a dose, take it as soon as you remember. Skip the dose if it is almost time for the next dose. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next dose at the usual time.

- **Possible side effects**

PSYQUET can have side effects.

Not all side effects reported for PSYQUET 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 healthcare professional for advice.

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If any of the following happens, stop taking PSYQUET and tell your doctor immediately or go to the nearest 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.
- Yellowing of the skin and eyes, also called jaundice, including nausea, vomiting, stomach pain and discomfort, loss of appetite, generally feeling unwell, fever, itching, light coloured stools and dark coloured urine. These symptoms might be an indication of a liver disease.
- If you have a condition called 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);
 - Acute Generalized Exanthematous Pustulosis (AGEP), small blisters filled with pus;
 - Erythema Multiforme (EM), skin rash with itchy-red irregular spots.

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

- Leg pain or tenderness of the thigh or calf, leg swelling, skin that feels warm to the touch.

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- Changes in the way your heart beats, for example if you notice it beating faster.
- Difficulty breathing.
- Signs of recurrent infection such as fever or sore throat.
- Less urine than is normal for you.

These are all serious side effects. You may need urgent medical attention. The frequency of these serious side effects is not known.

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

Side effects occurring frequently:

- Painful swollen breasts in men or irregular periods in women.
- Hypothyroidism, a condition where the thyroid levels in your blood are low, including symptoms like fatigue, increased sensitivity to cold, constipation, dry skin, weight gain, puffy face, hoarseness, muscle weakness.
- High levels of cholesterol or triglyceride (a type of fat) levels in your blood, weight gain, increased appetite, increased blood glucose levels.
- Abnormal dreams and nightmares, having suicidal thoughts and thinking about killing yourself.
- Headaches, sleepiness, drowsiness, restlessness, rigidity, slowness of movement, tremor, or irregular, jerky movements, feeling anxious, speaking with difficulty.
- Low blood pressure or dizziness on standing up, especially when getting up from a sitting or lying position.
- Abnormal or foul taste in your mouth, dry mouth, constipation, vomiting.
- Feeling exhausted, fever, irritability.

Side effects occurring less frequently:

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- Getting infections more often than you used to.
- Urinating more than usual.
- Low sodium levels in your blood, which may lead to confusion, seizures.
- Walking in your sleep.
- Pins and needles in your legs, involuntary movements of the face and jaw.
- Dry eyes, blurred vision.
- Ear pain.
- Runny nose.
- Difficulty in swallowing, nausea, vomiting, pulse rate faster than usual.
- Muscle pain or muscle weakness.
- Urinary infections.
- Inability to perform sexual activities, prolonged erection that is not sexually of origin, swelling of breasts, irregularities in the menstrual cycle.
- Fever, muscle rigidity, low body temperature.

Side effects with frequency unknown:

- Skin rash with irregular red spots (erythema multiforme).
- 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).
- 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).
- Symptoms of withdrawal may occur in new-born babies of mothers that have used quetiapine during their pregnancy.
- Disorder of the heart muscle (cardiomyopathy).

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- Inflammation of the heart muscle (myocarditis).
- Inflammation of blood vessels (Vasculitis), often with skin rash with small red or purple bumps

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 PSYQUET.

Suspected adverse reactions can also be reported directly to the HCR via

Patientsafety.sacg@novartis.com.

5. How to store PSYQUET

STORE ALL MEDICINES OUT OF REACH CHILDREN.

Store at or below 25 °C.

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 PSYQUET contains

The active substance is quetiapine fumarate.

Each PSYQUET 100 tablet contains quetiapine hemifumarate equivalent to 100 mg quetiapine.

Each PSYQUET 200 tablet contains quetiapine hemifumarate equivalent to 200 mg quetiapine.

Each PSYQUET 300 tablet contains quetiapine hemifumarate equivalent to 300 mg quetiapine.

The other ingredients are:

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Core:

Calcium hydrogen phosphate dehydrate, cellulose microcrystalline, lactose monohydrate, magnesium stearate, povidone, silica colloidal hydrated, sodium starch glycolate (type A).

Coating:

Opadry II white, iron oxide yellow (only for PSYQUET 100 tablet).

Opadry II white consists of: hypromellose, lactose monohydrate, macrogol 4000, titanium dioxide (E 171).

What PSYQUET looks like and contents of the pack

PSYQUET 100: A yellow, round film coated tablet with one sided breaking notch for tablet quarters.

PSYQUET 200: A white, round film coated tablet with one sided breaking notch for tablet quarters.

PSYQUET 300: A white, oval film coated tablet with a score line for tablet halves on both sides.

PSYQUET 100 tablets are packed as 90 tablets in either:

- Clear, transparent PVC/COC/PVDC/aluminium blisters or PVC/PE/PVDC/aluminium blisters in cartons. Each carton contains 9 blisters with 10 tablets per blister, or
- White HDPE securitainers.

PSYQUET 200 tablets are packed as 60 tablets in either:

- Clear, transparent PVC/COC/PVDC/aluminium blisters or PVC/PE/PVDC/aluminium blisters in cartons. Each carton contains 6 blisters with 10 tablets per blister, or
- White HDPE securitainers.

PSYQUET 300 tablets are packed as 60 tablets in either:

- Clear, transparent PVC/COC/PVDC/aluminium blisters or PVC/PE/PVDC/aluminium blisters in cartons. Each carton contains 6 blisters with 10 tablets per blister, or

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- White HDPE containers, or

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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Registration numbers

Psyquet 100: 43/2.6.5/0849

Psyquet 200: 43/2.6.5/0850

Psyquet 300: 43/2.6.5/0851

¹Company Reg. No.: 1990/001979/07

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