

PROPOSED AMENDED PATIENT INFORMATION LEAFLET (Clean)

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KIZOFRIN 25 mg (Tablet)

KIZOFRIN 100 mg (Tablet)

KIZOFRIN 200 mg (Tablet)

KIZOFRIN 300 mg (Tablet)

Quetiapine fumarate

Read all of this leaflet carefully before you start taking KIZOFRIN .

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

The active substance is quetiapine.

KIZOFRIN 25 mg:

Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 25 mg.

KIZOFRIN 100 mg:

Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 100 mg.

KIZOFRIN 200 mg:

Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 200 mg.

KIZOFRIN 300 mg:

Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 300 mg.

The other ingredients of **KIZOFRIN** are calcium hydrogen phosphate; cellulose microcrystalline; lactose; magnesium stearate; povidone; silica colloidal anhydrous; sodium starch glycolate and talc. The coating material of **KIZOFRIN 25 mg** contains hypromellose; iron oxide red (C.I. No: 77491); iron oxide yellow (C.I. No: 77492); macrogol / PEG 400 and titanium dioxide (C.I. No: 77891). The coating material of **KIZOFRIN 100 mg** contains hypromellose; iron oxide yellow (C.I.

No: 77492); macrogol / PEG 400 and titanium dioxide (C.I. No: 77891). The coating material of

KIZOFRIN 200 mg contains hypromellose; macrogol 400 and titanium dioxide (C.I. No: 77891).

The coating material of **KIZOFRIN 300 mg** contains hypromellose; macrogol 400 and titanium dioxide (C.I. No: 77891). The imprinting ingredients used on **KIZOFRIN 100 mg, KIZOFRIN 200 mg** and **KIZOFRIN 300 mg** contains ammonium hydroxide; iron oxide black (C.I. No: 77499); isopropyl alcohol; N-butylalcohol; propylene glycol and shellac glaze in ethanol.

2. WHAT KIZOFRIN ARE USED FOR

KIZOFRIN belongs to a group of medicines called anti-psychotics.

KIZOFRIN are used to treat some types of mental illness such as:

- Schizophrenia. Symptoms of schizophrenia include hallucinations (like hearing unexplained voices), strange and frightening thoughts, changes in how you act, and feeling alone and confused.
- Manic episodes that occur with a bipolar disorder. Symptoms of mania include effects on your mood and feeling very “high” or excited. You may feel that you need to sleep less than usual. You may also be more talkative and have racing thoughts or ideas. You may also feel more irritable than usual.

3. BEFORE YOU TAKE KIZOFRIN

Do not take KIZOFRIN :

- If you are hypersensitive (allergic) to quetiapine, or any of the other ingredients of **KIZOFRIN** .
- If you are pregnant or breast-feeding.
- In children and adolescents – Because the safety and effectiveness of **KIZOFRIN** has not been determined in this age group.
- If you have advanced liver and kidney problems.

Take special care with KIZOFRIN :

- Before taking **KIZOFRIN** , tell your doctor:

- If you have diabetes or are at risk of getting diabetes (e.g. if you are obese or have a family history of diabetes). If you have diabetes, your doctor will check your blood sugar levels

regularly while you are taking **KIZOFRIN** . If you are at risk for getting diabetes, your doctor will monitor you for symptoms of high blood sugar such as excessive thirst and fluid intake, passage of large volume of urine, excessive eating and weakness.

- If you have liver or kidney problems.
- If you have heart problems.
- If you have had a stroke.
- If you have low blood pressure.
- If you have ever had a fit (seizure).

- **KIZOFRIN** may cause lightheadedness or dizziness when getting up from a lying or sitting position, particularly when you first begin treatment. This is more likely to occur in elderly patients. Avoid getting up too fast from a sitting or lying position.

- **KIZOFRIN** may cause a condition called “tardive dyskinesia”. Contact your doctor straight away if you develop any of the following symptoms of tardive dyskinesia: uncontrollable movements, mainly of your face or tongue.

- **KIZOFRIN** may cause a condition called “neuroleptic malignant syndrome”. Contact your doctor straight away if you develop any of the following symptoms of neuroleptic malignant syndrome: extremely high body temperature, faster breathing, fast heart rate, sweating, stiff muscles, feeling very sleepy or faint, agitation; confusion; tremor (shakes); large increase in blood pressure.

- **KIZOFRIN** may cause a worsening of depression or suicidal thoughts and behaviour whether or not you are taking antidepressant medication. Contact your doctor straight away if you are experiencing this condition.

- If you are taking **KIZOFRIN** your doctor should be monitoring you at the beginning of your treatment or when you experience any changes in your dose to make sure you do not experience worsening of your symptoms or suicidality.

Taking KIZOFRIN with food and drink:

- **KIZOFRIN** can be taken with or without food.
- Be careful how much alcohol you drink. This is because the combined effect of **KIZOFRIN** and alcohol can make you feel sleepy.

Pregnancy and Breast-feeding:

KIZOFRIN must not be taken during pregnancy and breast-feeding. The safe use of **KIZOFRIN** during pregnancy and breast-feeding has not been established.

If you are pregnant or breast-feeding your baby while taking **KIZOFRIN** , please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

KIZOFRIN may make you feel sleepy. Do not drive or use any tools or machines until you know how **KIZOFRIN** affect you.

Important information about some of the ingredients of KIZOFRIN

KIZOFRIN contains lactose. Patients with rare hereditary problems of galactose intolerance, lapp lactase efficiency, or glucose-galactose malabsorption should not take **KIZOFRIN** .

Taking other medicines with KIZOFRIN :

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

(This includes complementary or traditional medicines).

- Alcohol.
- Barbiturates (medicines for epilepsy).
- Thioridazine (another anti-psychotic medicine).
- Rifampicin (for tuberculosis).
- Medicines for seizures, such as carbamazepine, phenytoin, phenobarbital or sodium valproate.
- Medicines for depression or mental illness, such as imipramine, haloperidol, risperidone or fluoxetine.
- Erythromycin (an antibiotic medicine)
- Certain antifungal medicines, such as fluconazole, itraconazole and ketoconazole.

- Medicines used to treat high blood pressure.
- Levodopa (for the treatment of Parkinson's disease)
- Medicines known to make the QT interval (a time interval on an ECG ie. electrocardiogram) longer.

If you are using any of these medicines, you may not be able to take **KIZOFRIN**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **KIZOFRIN** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE KIZOFRIN

Always take **KIZOFRIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **KIZOFRIN** is too strong or too weak, talk to your doctor or pharmacist.

- **KIZOFRIN** should be taken twice a day, with or without food.
- **Adults:**
 - Your doctor will decide on your starting dose and may gradually increase it.
 - After this the dose will usually be between 150 mg and 800 mg each day. It depends on your illness and needs.
- **Elderly people:**
 - If you are elderly your doctor may give you a lower dose.
- **Kidney and liver problems:**
 - If you have kidney and liver problems your doctor may give you a lower dose.

If you take more KIZOFRIN than you should:

The symptoms of overdose include sleepiness, increased rate of heart beat and low blood pressure.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek contact the nearest hospital.

If you forget to take KIZOFRIN :

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 dose.

5. POSSIBLE SIDE-EFFECTS

KIZOFRIN can have side-effects.

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

- Hives/rash; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you have had a serious allergic reaction to **KIZOFRIN** . You may need urgent medical attention or hospitalization.

- Neuroleptic malignant syndrome. Symptoms of neuroleptic malignant syndrome include: extremely high body temperature, faster breathing, fast heart rate, sweating, stiff muscles, feeling very sleepy or faint, agitation; confusion; tremor (shakes); large increase in blood pressure (manifesting as symptoms of headache, blurred vision, vomiting and nosebleeds).
- **KIZOFRIN** may cause a condition called "Tardive dyskinesia". Symptoms of tardive dyskinesia include: uncontrollable movements, mainly of your face or tongue.
- Seizures (fits)
- Painful erection of the penis which lasts for hours.
- Changes in vision

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

- feeling sleepy (this may go away with time, as you keep taking **KIZOFRIN**); dizziness; dry mouth; lack of energy; constipation; increased rate of heart beat; low blood pressure when standing (this may make you feel dizzy or faint); indigestion; weight gain; fainting; swelling of hands and feet due to retained fluid; stuffy nose; fever; lack of appetite; drowsiness; difficulty speaking;

- anxiety; dry eyes; ear pain; (rapid irregular action of heartbeat; low blood pressure; high blood pressure; inflammation of the throat; abdominal pain; diarrhoea (frequent or loose watery stools); increased sweating; muscle pain; bladder or kidney infections; irregular menstrual periods; unexpected production of breast milk (galactorrhoea); headache; flu-like symptoms; back pain; chest pain.
- Abnormal muscle movements. These include difficulty starting muscle movements; shaking; feeling restless or muscle stiffness without pain.

Some side-effects are only seen when a blood test is taken. These include too few white blood cells, increased number of a certain type of white blood cells in blood, changes in the amount of certain fats (triglycerides and total cholesterol) in the blood, decreases in thyroid hormone, increases in liver enzymes and increases in the amount of the hormone prolactin in the blood.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **KIZOFRIN** .

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

6. STORING AND DISPOSING OF KIZOFRIN

Store at or below 30 °C (room temperature). Do not remove the blister strip from the carton until required for use. Keep the container well closed.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF KIZOFRIN

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: KIZOFRIN 25, 100, 200, 300 mg TABLETS
Dosage form and strength: TABLET 25, 100, 200, 300 mg



Submitted: 26/02/2021

KIZOFRIN 25 mg:

Blister Pack:

Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.

Pack sizes: 30's – Each carton contains 3 blisters of 10 tablets each.

90's – Each carton contains 9 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE container with white opaque closure, with induction sealing wad.

Pack sizes: 30's - One HDPE container contains 30 tablets.

90's - One HDPE container contains 90 tablets

KIZOFRIN 100 mg:

Blister Pack:

Tablets are packed in white opaque PVC film and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 90's – Each carton contains 9 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE container with white opaque closure, with induction sealing wad.

Pack size: 90's - One HDPE container contains 90 tablets.

KIZOFRIN 200 mg:

Blister Pack:

Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE container with white opaque closure, with induction sealing wad.

Pack size: 30's - One HDPE container contains 30 tablets.

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: KIZOFRIN 25, 100, 200, 300 mg TABLETS
Dosage form and strength: TABLET 25, 100, 200, 300 mg



Submitted: 26/02/2021

KIZOFRIN 300 mg:

Blister Pack:

Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE container with white opaque closure with induction sealing wad.

Pack size: 30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF KIZOFRIN

KIZOFRIN 25 mg:

Peach, round, biconvex, film-coated tablets debossed with 'E 52' on one side and plain on the other side.

KIZOFRIN 100 mg:

Yellow, round, biconvex, film-coated tablets imprinted with 'E 53' on one side and plain on the other side.

KIZOFRIN 200 mg:

White, round, biconvex, film-coated tablets imprinted with 'E 55' on one side and plain on the other side.

KIZOFRIN 300 mg:

White, capsule shaped, biconvex, film-coated tablets imprinted with 'E 56' on one side and plain on the other side.

9. REGISTRATION NUMBER

TBA

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: KIZOFRIN 25, 100, 200, 300 mg TABLETS
Dosage form and strength: TABLET 25, 100, 200, 300 mg



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Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

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