SIZONORM

(Quetiapine Tablets USP 25, 100, 200mg) *Consumer Medication Information Leaflet (RiMUP)*

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This leaflet answers some common questions about **SIZONORM**.
All medicines have risks and benefits. Your doctor has weighed the risks of you taking **SIZONORM** against the benefits it is expected to have for you.
Keep this leaflet with the medicine.
You may need to read it again.

What SIZONORM is used for

SIZONORM contains a substance called quetiapine which is used to treat conditions such as:

- 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: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Bipolar depression: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

How SIZONORM works

Quetiapine belongs to a group of medicines called anti-psychotics. It helps to correct chemical imbalances in the brain.

Before you use SIZONORM

When you must not use it

Do not take SIZONORM:

- if you are allergic to quetiapine or any of the other ingredients of this medicine
- if you are taking any of the following medicines:
  - Some medicines for HIV (protease inhibitors)
  - Azole medicines (for fungal infections)
  - Erythromycin or clarithromycin (for infections)
  - Nefazodone (for depression).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes before taking SIZONORM:

- If you or someone in your family, have or have had any heart problems, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart
- Have or are at risk of having diabetes (eg. Being overweight or family history of diabetes). Your doctor should check your blood sugar before you start taking **SIZONORM** and regularly during treatment.
- 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 a history of blood clots, as medicines like these have been associated with formation of blood clots.
- If you have ever had a fit (seizure)
- If you have a history of alcohol or drug abuse.
- If you have problems with your liver.
- If you have low blood pressure
- If you are at risk of aspiration pneumonia (accidental inhalation of food with risk of pneumonia)
- If you have had a stroke, especially if you are elderly.
- 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 know that 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 are an elderly person with dementia (loss of brain function). It had been reported that elderly individuals with dementia-related psychosis are at an increased risk of death compared to people who do not receive antipsychotic medicines.

Tell your doctor as soon as possible if you experience any of the following after taking SIZONORM:

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness ("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.
- If you are an elderly person with dementia (loss of brain function). If you are, quetiapine should not be taken because the group of medicines that quetiapine belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- 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 quetiapine to be stopped
- 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 and 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. You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet.

A decrease in "good cholesterol" (HDL-C), an increase in a type of fat in your blood called triglycerides, and an increase in your blood sugar has been reported in patients taking quetiapine..

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

Pregnancy and Lactation
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby ask your doctor for advice before taking this medicine. You should not take quetiapine during pregnancy unless this has been discussed with your doctor. Quetiapine should not be taken if you are breast-feeding.

The following symptoms which can represent withdrawal may occur in newborn babies of mothers that have used quetiapine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Children and adolescents
The effects of quetiapine have only been studied in children aged between 10 and 17 years with mania and in children aged between 13 and 17 years with schizophrenia. There is not enough information on its effects in children to recommend its use in other age groups or for other conditions.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **SIZONORM** may interfere with each other. These include:

- Epilepsy medicines (like phenytoin or carbamazepine).
- Medicines (called "anti-cholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- Medicines that have an impact on the way your heart beats, for example, drugs 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).
- Thioridazine or lithium (other anti-psychotic medicine).
- Medicines that can cause constipation.
- Grapefruit juice
- Antidepressants (such as Imipramine and fluoxetine)

How to use SIZONORM

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to use
Your doctor will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

Quetiapine is usually started as a low dose that will be gradually increased by your doctor. This will depend on various factors including your age, condition being treated, other medical conditions (eg liver problems), other medicines you are taking and how you may react to quetiapine.

Your doctor will monitor your condition and may change your dose depending on how you respond to it.

When to use it
Quetiapine is taken once or twice a day depending on your condition. Your doctor will tell you how you should take it.

Swallow your tablets whole with a full glass of water. You can take them with or without food.

How long to use it
Continue taking the tablets for as long as your doctor tells you.

Quetiapine helps control your condition, but does not cure it. Therefore you must take it every day.

If you forget to use it

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 use too much (overdose)
If you take more quetiapine tablets than prescribed by your doctor, you may feel sleepy, feel dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Keep the quetiapine tablets with you so that doctor knows what you have taken.

While you are using SIZONORM

Keep all of your doctor's appointments so that your progress can be checked.

Things you must do
If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking it.

Tell your doctor or mental health professional immediately, or go to the nearest hospital, if you have any of the following suicidal thoughts or other mental/mood changes:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the early stages of treatment until the effect of the medicine becomes apparent. All mentions of suicide or violence must be taken seriously.
If you become pregnant while taking it, tell your doctor immediately.

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

Things you must not do

Do not stop taking it, or change the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. You may experience nausea, vomiting or insomnia (sleeping difficulty), headache, diarrhea, dizziness and irritability.

Do not give it to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Your tablets may make you feel sleepy. Do not drive or use any tools or machines until you know how the tablets affect you. Children should be careful when riding bicycles or climbing trees.

Do not drink grapefruit juice while you are taking quetiapine. It can affect the way the medicine works.

If it makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Be careful when drinking alcohol while you are taking quetiapine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SIZONORM.

Ask your doctor or pharmacist to answer any questions you may have.

Serious side effects

If any of the following happens, stop taking SIZONORM and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- Severe allergic reaction (may include severe difficulty in breathing, shock, swelling of the face, lips, tongue or other parts of the body, skin rash, hayfever, or you may feel faint)
- A combination of fever, sweating, stiff muscles, feeling very drowsy or faint ("neuroleptic malignant syndrome").
- Thoughts of suicide and worsening of your depression
- A long-lasting and painful erection (priapism).
- Diabetes mellitus: Increase in blood sugar level and/or symptoms of high blood sugar (eg. increased thirst, increased hunger and frequent urination)
- Worsening of pre-existing diabetes.

The above list includes serious side effects that may require urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects

- weight gain
- dizziness, headache, dry mouth
- feeling sleepy
- abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain
- discontinuation symptoms (symptoms which occur when you stop taking quetiapine) include not being able to sleep, feeling sick, headache, diarrhoea, being sick, dizziness and irritability

Common side effects

- feeling more hungry
- abnormal dreams and nightmares
- disturbance in speech and language
- fast or irregular heartbeats
- blurred vision
- low blood pressure when standing up
- shortness of breath
- constipation, indigestion, vomiting
- unusual weakness
- swelling of hands, ankles or feet
- irritability
- fever

Uncommon side effects

- Fits (seizures)
- Restless legs syndrome (unpleasant leg sensations and an intense urge to move the legs)
- Difficulty swallowing
- Fainting (may lead to falls)
- Runny or stuffy nose (inflammation of nose mucous membrane)
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Urinary retention (difficulty or inability to pass urine)
- Sleep apnoea (trouble breathing during sleep)

Rare side effects

- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Walking, talking, eating or other activities while you are asleep
- Body temperature decreased (hypothermia)
- Inflammation of the liver (with or without jaundice)

Very rare side effects

- Anaphylaxis (severe form of allergic reaction; may include severe difficulty breathing and shock)

Unknown side effects

- 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.

The following side effects can also occur with **SIZONORM**, and may be 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 **SIZONORM**.
- 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 type of white blood cell 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 **SIZONORM**.
- Changes in the amount of fatty substances (lipid levels such as triglycerides and cholesterol) in the blood.
- Increase in the amount of 'creatine phosphokinase', a substance in the muscles.
- Increase in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination).
- Increase in the amount of the hormone prolactin in the blood. Rarely 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.

Additional side effects in children and adolescents
The same side effects that may occur in adults may also occur in children and adolescents.
The following side effects have been seen more often in children and adolescents or have not been seen in adults:

Very common side effects
- increase in the amount of a hormone called prolactin, in the blood
- increased appetite
- abnormal muscle movement
- increase in blood pressure
- vomiting

Common side effects
- Fainting
- runny or blocked nose
- irritability

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of SIZONORM

Storage
Store below 30ºC,
Keep out of the reach and sight of children.

Disposal

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- Do not take your tablets after the expiry date on the container. Return all out of date tablets to your pharmacist.

Product Description

What SIZONORM looks like
SIZONORM 25
Peach, round, biconvex, film coated tablets plain on both sides.

SIZONORM 100
Yellow, round, biconvex, film coated tablets plain on one side and Break-line on other side.

SIZONORM 200
White, round, biconvex, film coated tablets plain on one side and Break-line on other side.

Active ingredient: quetiapine
Each tablet contains
Quetiapine Fumarate USP equivalent to Quetiapine….. 25/100/200mg

Inactive ingredients: Silicified microcrystalline cellulose, Crospovidone, Colloidal anhydrous silica, Anhydrous citric acid, Polysorbate 80, Silicon dioxide, Magnesium stearate, Opadry II 33F58617 white (For 200mg), Opadry II 33F84535 Pink (for 25mg), Opadry II 33F82557 yellow (for 100mg), Purified water.

Packing: SIZONORM Tablet 25mg, 100mg and 200mg is available in blister of 3 x 10 tablets with Show box along with pack insert. The scored line is just for identification purpose and not meant to be halved.

For 25 mg - MAL21026010AZ
For 100mg - MAL21026011AZ
For 200mg - MAL21026012AZ

Manufacturer

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Product Registration Holder
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