Kventiax prolonged-release tablets

Quetiapine (**50 mg, 200 mg, 300 mg, 400 mg)**

What is in this leaflet

What Kventiax is used for

Kventiax can be used to treat:

- Adults with schizophrenia, a disease with symptoms, such as hallucinations (for example unexplained voices), strange and frightening thoughts, changes in behaviour, feeling alone and confused.
- Adults with bipolar disorder, either in a moderate to severe manic or in a depressive state. In a manic state people may find they are more talkative and have racing thoughts or ideas whereby they feel 'high' or excited. They may also feel unusually irritable, sad and guilty, lack energy, lose their appetite and/or can't sleep. Whereas depressed adults who do not feel high or excited, these individuals have prolonged periods of feeling sad, lack energy, are often tearful, and have changes in sleep or appetite.
- Kventiax can be used to prevent relapse in individuals with schizophrenia whose condition has been stabilized.
- Kventiax can be used to prevent relapse in individuals with bipolar disorder whose moderate to severe manic or depressive episodes were successfully treated with quetiapine.
- Kventiax can be used to treat recurrent major depressive disorder in individuals for whom other antidepressant treatments are not suitable (either because they do not work well or because of side effects).

Your doctor may continue to give you Kventiax even when you are feeling better to prevent your symptoms from returning.

How Kventiax works

Kventiax contains quetiapine h e m i fumarate. Kventiax belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain.

Before you use Kventiax

- *When you must not use it*

Do not take Kventiax if you have ever had an allergic reaction to Kventiax or to any of its ingredients (see section **Product Description**).

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

- HIV-protease inhibitor for Human Immunodeficiency Virus (HIV)
- azole medicines (for fungal infections)
- erythromycin or clarithromycin (for infections)
- nefazodone (for depression)

If you are not sure, talk to your doctor or pharmacist before taking Kventiax.

- *Before you start to use it*

Take special care with Kventiax. If you go into hospital let the medical staff know you are taking Kventiax. Tell your doctor:

- if you have any health problems
- if you are at risk for lung inflammation that occurs after you inhale foreign matter
- if you have rare hereditary sugar intolerance problems
- if you have low blood pressure or have had a stroke
- 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 problems with your liver
- 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 ever had a seizure (fit).
- if you are an elderly person with dementia (loss of brain function). It has been reported that elderly individuals with dementia-related psychosisare at an increased risk of death compared to people who do not receive antipsychotic medicines.
- if you have or you are at risk of diabetes (e.g. family history of diabetes, high blood sugar during pregnancy, obesity) (see also *'Things to be careful of'*)
- if you have a history of alcohol or drug abuse
- 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 had a condition where you cannot 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 medical conditions
- if you have depression or other conditions that are treated with antidepressants. The use of these medicines together with Kventiax can lead to serotonin syndrome, a potentially life-threatening condition (see also *Taking other medicines*)

Pregnancy and lactation

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant.

The following *extrapyramidal* and/or *withdrawal symptoms* may occur in newborn babies, of mothers that have used Kventiax in the last trimester (last three months of their pregnancy): agitation, muscle stiffness and/or weakness, shaking, sleepiness, breathing problems, and difficulty in feeding. If

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your baby develops any of these symptoms you may need to contact your doctor.

Avoid this medicine if you are breast-feeding. This is because the medicine may pass into the mother's milk.
Ask your doctor for advice before taking any medicine if you are pregnant or breast-feeding.

- *Taking other medicines*
Tell your doctor if you are taking any other medicines, including any that you buy without a prescription particularly:
- medicines listed under *When you must not use it*
- grapefruit juice
- antidepressants. These medicines may interact with Kventiax 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
- thioridazine, for mental illness
- medicines for epilepsy (such as phenytoin or carbamazepine)
- medicines for high blood pressure
- medicines (called "anticholinergics") that affect the way nerve cells function in order to treat certain medical conditions
- medicines that cause constipation
- barbiturates (for sleeplessness)

Please note that these statements may also apply to products used some time ago.

How to use Kventiax
Follow your doctor's instructions about when and how to take your tablets. Please READ THE LABEL on the container. This will also tell you how many tablets to take and when you should take them. Ask your doctor, nurse or pharmacist if you are not sure.

- *How much to use*
Kventiax is usually started as a low dose that will be monitored and gradually increased by your doctor. For maintenance dose, your doctor may adjust your daily dose of Kventiax between 50 mg and 800 mg depending on your disease, age, and individual treatment and needs.

If you have liver disease, or you are elderly, your doctor may start you on a lower dose and increase it more gradually.

Kventiax is not approved for children or adolescents under 18 years of age.

- *When to use it*
You will take your tablets once a day.
Take your tablets without food (at least one hour before a meal or at bedtime, your doctor will tell you when). Swallow your tablets whole with a drink of water. Do not split, chew or crush the tablets.

- *How long to use it*
Continue taking the tablets for as long as your doctor tells you. Kventiax helps control your condition, but does not cure it. Therefore you must take it every day.

- *If you forget to use it*
If you miss a dose, take the dose as soon as you remember. Then take the next dose at the usual time. Do not take a double dose.

- *If you use too much (overdose)*
If you take more than your normal dose, contact a doctor or the nearest hospital, immediately. Symptoms of an overdose may include: drowsiness and sedation, rapid heartbeat and low blood pressure.

While you are using Kventiax
- *Things you must do*
If you have the impression that the effect of Kventiax is too strong or too weak, talk to your doctor or pharmacist. Tell your doctor immediately if you become pregnant while using this medication

- *Things you must not do*
Do not stop taking your tablets even if you are feeling better, unless your doctor tells you. If your doctor decides that you need to stop taking Kventiax, he/she will reduce the dose gradually over a period of at least one to two weeks.

If you stop taking Kventiax abruptly you may experience nausea, vomiting or insomnia (sleeping difficulty), headache, diarrhoea, dizziness and irritability.

- *Things to be careful of*
Driving and using machines
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.
Effect on Urine Drug Screens
If you are having a urine drug screen, taking Kventiax may cause positive results for methadone or certain medicines for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. Confirmation of the results by more specific tests is recommended.

Diabetes
If you suffer from a high level of sugar in the blood (diabetes) your doctor may regularly check your level of sugar in the blood.

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

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 first few weeks but sometimes

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longer. You may be more likely to think like this if:
- You have previously had thoughts about killing or harming yourself.
- You are a child, teenager or young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behaviour in children, teenagers, or young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

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.

Severe cutaneous adverse reactions (SCARs)
Severe skin related adverse reactions including Stevens-Johnsons Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalized Exanthematous Pustulosis (AGEP), Erythema Multiforme (EM) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can be life threatening, have been reported with the use of this medicine. These serious skin reactions may present with one or more combination of the following symptoms: widespread blistering (may be filled with pus) or peeling of the skin, flu like symptoms, blood abnormalities (increase in a type of white blood cells), swollen glands (enlarged lymph nodes) or itchy skin rash with pink-red irregular spots.

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

Kventiax contains lactose and sodium

Kventiax contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

50 mg prolonged-release tablets: This medicine contains 8.44 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.42% of the recommended maximum daily dietary intake of sodium for an adult.

200 mg prolonged-release tablets: This medicine contains 19.38 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.97% of the recommended maximum daily dietary intake of sodium for an adult.

300 mg prolonged-release tablets: This medicine contains 29.06 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.45% of the recommended maximum daily dietary intake of sodium for an adult.

400 mg prolonged-release tablets: This medicine contains 23.46 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.17% of the recommended maximum daily dietary intake of sodium for an adult.

Side effects
Like all medicines, Kventiax can cause side effects, although not everybody gets them. Tell your doctor if any of the following side effects bothers you. Contact your doctor immediately or go to the nearest hospital if any of the following events happen to you.
- A combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called "neuroleptic malignant syndrome")
- Fits (seizures)
- Priapism (long-lasting and painful erection)
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia)

Tell your doctor as soon as possible 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 Kventiax 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.

Side effects that are very common (more than 10 of every 100 individuals are likely to have them):
- Dizziness (may lead to falls)
- Feeling sleepy (this may go away whilst you continue taking your tablets) (may lead to falls)
- Dry mouth
- Headache
- Weight gain
- You may have abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
  Discontinuation symptoms (i.e., symptoms which occur upon stopping Kventiax) include vomiting, dizziness, nausea, headache, diarrhoea, insomnia and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable).

Side effects that are common (1 to 10 of every 100 individuals are likely to have them):
- Rapid heart beat
- Feeling like your heart is pounding, racing or has skipped beats
- Constipation
- Indigestion
- Feeling weak
- Swelling of arms or legs
- Low blood pressure in standing position, which may result in dizziness or feeling faint (may lead to falls)
- Blurred vision
- Abnormal dreams and nightmares
- Irritability

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- Increased appetite
- Disturbance in speech
- Shortness of breath
- Vomiting (mainly in the elderly)
- Fever

Side effects that are uncommon (less than 1 of every 100 individuals are likely to have them):

- Allergic reactions that may include weals and swelling of the skin
- Fits (seizures)
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- 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.
  - Difficulty or inability to pass urine (urinary retention)
  - Trouble breathing during sleep (sleep aponea)
- Confusion

Side effects that are rare (less than 1 of every 1000 individuals are likely to have them):

- Combination of fever, very marked drowsiness, muscle stiffness, marked increase in heartbeats or blood pressure and reduced consciousness (a disorder called "neuroleptic malignant syndrome")
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Priapism (long-lasting and painful erection)
- Walking, talking, eating or other activities while you are asleep
- Body temperature decreased (hypothermia)
- Inflammation of the liver (with or without jaundice)

Side effects that are very rare (less than 1 of every 10000 individuals are likely to have them):

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

Side effects that are of unknown frequency (cannot be estimated from the available data):

- 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)) and a severe form of skin rash with itchy pink-red irregular spots (a condition known as Erythema multiforme (EM)) may occur.
- Formation of a gum like sticky mass of tablets in the stomach may occur only when you take more Kventiax than you should. Please contact your doctor immediately as it may require endoscopy for removal of the sticky mass.
- Disorder of the heart muscle (cardiomyopathy)
- Inflammation of the heart muscle (myocarditis)
- Inflammation of blood vessels (Vasculitis), often with skin rash with small red or purple bumps

If you have any of the above side effects contact your doctor.

The following side effects can also occur with Kventiax, 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 Kventiax.
- 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 Kventiax.
- 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 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.

<u>*Children and adolescents (10 to 17 years of age)*</u>

Side effects that have occured in clinical trials of Kventiax in children and adolescents (10 to 17 years of age). Tell your doctor if any of the following side efffects bother you.

Side effects that are very common (more than 10 of every 100 individuals are likely to have them):

- Increase in blood pressure
- Increase in the amount of the hormone prolactin in the blood. rarely this may lead to:
  - Boys and girls to have swelling of breasts and unexpectedly produce breast milk
  - Girls to have no monthly period or irregular periods
- Increased appetite
- Vomiting

Side effects that are common (1 to 10 of every 100 individuals are likely to have them):

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- Runny or stuffy nose (inflammation of the nose mucous membrane)
- Fainting (may lead to falls)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.
You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Kventiax

- *Storage*

  Keep out of the sight and reach of children.

  Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

  Store in the original package in order to protect from moisture.
  Store below 30°C.

- *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.

Product Description

- *What it looks like*

  50 mg prolonged-release tablets are white to almost white, capsule shaped, slightly biconvex, film-coated tablets with bevelled edges, engraved with 50 on one side.
  200 mg prolonged-release tablets are yellow brown, oval, biconvex, film-coated tablets.
  300 mg prolonged-release tablets are pale brownish yellow, capsule shaped, biconvex, film-coated tablets.
  400 mg prolonged-release tablets are white to almost white, capsule shaped, biconvex, film-coated tablets, engraved with 400 on one side.

- *Ingredients*

  - Active ingredient(s)

The active substance is quetiapine.
50 mg prolonged-release tablets:
Each prolonged-release tablet contains 50 mg quetiapine (as quetiapine hemifumarate).
200 mg prolonged-release tablets:
Each prolonged-release tablet contains 200 mg quetiapine (as quetiapine hemifumarate).
300 mg prolonged-release tablets:
Each prolonged-release tablet contains 300 mg quetiapine (as quetiapine hemifumarate).
400 mg prolonged-release tablets:
Each prolonged-release tablet contains 400 mg quetiapine (as quetiapine hemifumarate).

  - Inactive ingredients

The other ingredients of 50 mg and 400 mg prolonged-release tablets are hypromellose, lactose monohydrate, microcrystalline cellulose, sodium citrate dihydrate and magnesium stearate in the tablet core and hypromellose, titanium dioxide (E171) and macrogol in the tablet coating. See section *"Kventiax contains lactose and sodium"*.
The other ingredients of 200 mg and 300 mg prolonged-release tablets are hypromellose, lactose monohydrate, microcrystalline cellulose, disodium phosphate dihydrate and magnesium stearate in the tablet core and polyvinyl alcohol, titanium dioxide (E171), macrogol, talc and yellow iron oxide (E172) in the tablet coating. See section *"Kventiax contains lactose and sodium"*.

Kventiax is available in packs containing 60 prolonged-release tablets in blisters.

MAL number(s):
MAL*******
MAL*******
MAL*******
MAL*********

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