

**Teva Pharmaceuticals (Pty) Ltd**

**Product name:** Quetiapine 50 / 200 / 300 / 400 Teva

**Dosage form and strength:** Film-coated tablet; 50 mg; 200 mg; 300 mg; 400 mg quetiapine

**Registration Number:** 47/2.6.5/0657; 47/2.6.5/0658; 47/2.6.5/0659; 47/2.6.5/0660

## **PATIENT INFORMATION LEAFLET:**

**SCHEDULING STATUS:** **S5**

**QUETIAPINE 50 TEVA** (50 mg film-coated tablets)

**QUETIAPINE 200 TEVA** (200 mg film-coated tablets)

**QUETIAPINE 300 TEVA** (300 mg film-coated tablets)

**QUETIAPINE 400 TEVA** (400 mg film-coated tablets)

**Quetiapine fumarate**

**Sugar free**

**Read all of this leaflet carefully before you start taking QUETIAPINE TEVA.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- QUETIAPINE TEVA 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 THE LEAFLET:**

- 1. WHAT QUETIAPINE TEVA IS AND WHAT IT IS USED FOR**
- 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE QUETIAPINE TEVA**
- 3. HOW TO USE QUETIAPINE TEVA**
- 4. POSSIBLE SIDE EFFECTS**
- 5. HOW TO STORE QUETIAPINE**
- 6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **1. WHAT QUETIAPINE TEVA IS AND WHAT IT IS USED FOR:**

**Teva Pharmaceuticals (Pty) Ltd****Product name:** Quetiapine 50 / 200 / 300 / 400 Teva**Dosage form and strength:** Film-coated tablet; 50 mg; 200 mg; 300 mg; 400 mg quetiapine**Registration Number:** 47/2.6.5/0657; 47/2.6.5/0658; 47/2.6.5/0659; 47/2.6.5/0660

QUETIAPINE TEVA contains the active substance quetiapine.

This belongs to a group of medicines called antipsychotics. QUETIAPINE TEVA can be used to treat several illnesses, 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.
- Preventing relapse in stable schizophrenic patients.
- Bipolar disorder:
  - Mania associated with bipolar disorder: you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
  - Depressive episodes associated with bipolar disorder: you may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.
  - Preventing recurrence in the maintenance treatment of bipolar disorder as monotherapy or in combination with other medicine.
- Major depressive episodes in major depressive disorder.
- Preventing relapse in stable major depressive disorder patients who have been maintained on QUETIAPINE TEVA.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE QUETIAPINE TEVA:**

### **Do not take QUETIAPINE TEVA:**

- if you are hypersensitive (allergic) to QUETIAPINE fumarate or any of the other ingredients of QUETIAPINE TEVA
- if you are taking any of the following medicines:
  - some medicines for HIV
  - azole medicines (for fungal infections)
  - erythromycin or clarithromycin (for infections)
  - nefazodone (for depression)

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- if you are pregnant or breastfeeding your baby
- if you are a child (10 to 12 years) or adolescent (13 to 17 years) as safety and efficacy have not been established
- if you suffer from advanced liver or renal dysfunction as safety has not been demonstrated.

**Warnings and precautions:**

Take special care with QUETIAPINE TEVA.

Talk to your doctor or pharmacist before taking QUETIAPINE TEVA if:

- you have problems with your liver
- 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 or if you are taking any medicines that may have an impact on the way your heart beats
- you have low blood pressure
- 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’)
- you have ever had a fit (seizure)
- 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)
- 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
- you have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking QUETIAPINE TEVA

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- you are an elderly person with dementia (loss of brain function). If you are, QUETIAPINE TEVA should not be taken because the group of medicines that QUETIAPINE TEVA belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia
- you have had a stroke, especially if you are elderly
- 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
- you have or have had problems with alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking QUETIAPINE TEVA:

- 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
- a combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called ‘neuroleptic malignant syndrome’). Immediate medical treatment may be needed
- weight problems, you and your doctor should check your weight regularly
- a long-lasting and painful erection (priapism).

These conditions can be caused by QUETIAPINE TEVA.

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 QUETIAPINE TEVA 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.

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If you are depressed, 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. Information from clinical trials of QUETIAPINE treatment in patients with major depressive disorder has shown an increased risk of self-harm and suicidal thoughts in patients aged 25 to 64 years without a history of self-harm if you use QUETIAPINE TEVA with other antidepressants.

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

**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 Generalised Exanthematous Pustulosis (AGEP), small blisters filled with pus

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- Erythema Multiforme (EM), skin rash with itchy-red irregular spots.

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

**Children and adolescents:**

Children and adolescents younger than 18 years should not take QUETIAPINE TEVA.

**Other medicines and QUETIAPINE TEVA:**

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

Do not take QUETIAPINE TEVA with the following medicines:

- some medicines for HIV
- azole medicines (for fungal infections)
- erythromycin or clarithromycin (for infections)
- nefazodone (for depression)

Tell your doctor if you are taking any of the following medicines:

- medicines (called ‘anti-cholinergics’) that affect the way nerve cells function in order to treat certain medical conditions
- epilepsy medicines (like phenytoin or carbamazepine)
- medicines that can cause constipation
- thioridazine (other anti-psychotic 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).

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- be careful how much alcohol you drink. This is because the combined effect of QUETIAPINE TEVA and alcohol can make you sleepy
- do not drink grapefruit juice while you are taking QUETIAPINE TEVA. It can affect the way the medicine works.

**Pregnancy, breastfeeding and fertility:**

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 healthcare provider for advice before taking QUETIAPINE TEVA.

You should not take QUETIAPINE TEVA during pregnancy or when breastfeeding your baby.

**Fertility:**

No human data available.

**Driving and using machines:**

QUETIAPINE TEVA may make you feel sleepy.

It is not always possible to predict to what extent QUETIAPINE TEVA may interfere with your daily activities. You should ensure that you do not engage in the driving a vehicle or use machines until you are aware of the measure to which QUETIAPINE TEVA affects you.

**3. HOW TO TAKE QUETIAPINE TEVA:**

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

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

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Your doctor will decide on your starting dose. The maintenance dose (daily dose) will depend on your illness and needs but will usually be between 150 mg and 800 mg.

You will take your tablets once a day.

Do not split, chew or crush the tablets.

Swallow your tablets whole with a drink of water.

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

**Liver problems:**

If you have liver problems your doctor may change your dose.

**Elderly people:**

If you are elderly your doctor may change your dose.

**Use in children and adolescents:**

QUETIAPINE TEVA should not be used by children and adolescents aged under 18 years.

Your doctor will tell you how long your treatment with QUETIAPINE TEVA will last. Do not stop treatment early because you feel better. If you have the impression that the effect of QUETIAPINE TEVA is too strong or too weak, tell your doctor or pharmacist.

**If you take more QUETIAPINE TEVA than you should:**

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

**If you forget to take a dose of QUETIAPINE TEVA:**

Do not take a double dose to make up for forgotten individual doses.

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**If you stop taking QUETIAPINE TEVA:**

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

Your doctor may suggest you reduce the dose gradually before stopping treatment.

**4. POSSIBLE SIDE EFFECTS:**

QUETIAPINE TEVA can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to QUETIAPINE TEVA. 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:*

- thoughts of harming or killing yourself at any time

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- rapid heartbeat
- feeling like your heart is pounding, racing or has skipped beats

*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
- 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. If you notice any of these symptoms seek medical advice immediately
- yellowing of the skin and eyes (jaundice)
- a serious allergic skin reaction, including rash, hives, blisters on the skin/peeling skin called Stevens-Johnson syndrome
- a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called ‘neuroleptic malignant syndrome’).

*Side effects with unknown frequency:*

- disorder of the heart muscle (cardiomyopathy)
- inflammation of the heart muscle (myocarditis)
- stroke
- 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). Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome)

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- rapid appearance of areas of red skin studded with small pustules [small blisters filled with white/yellow fluid called Acute Generalised Exanthematous Pustulosis (AGEP)]
- inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps.

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:*

- decreases in the number of certain types of blood cells
- increases in a type of white blood cells (neutrophils)
- increases in the amount of the hormone prolactin in the blood
- changes in the amount of thyroid hormones in your blood
- increases in the amount of certain fats (triglycerides and total cholesterol)
- decreased 'good cholesterol' (HDL) levels
- weight gain
- feeling hungrier
- increased levels of sugar in the blood
- abnormal dreams and nightmares
- headache
- feeling sleepy (this may go away with time, as you keep taking QUETIAPINE TEVA) (may lead to falls)
- disturbance in speech and language
- blurred vision
- low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls)
- shortness of breath
- dry mouth, constipation, upset stomach (indigestion), vomiting
- increases in the amount of liver enzymes measured in the blood

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- feeling weak
- feeling irritated
- swelling of arms or legs
- fever.

*Less frequent side effects:*

- deficiency of platelets in the blood and decreased platelet count
- deficiency of red blood cells
- you have too few neutrophils, a type of white blood cells
- decrease in certain thyroid function levels
- abnormally low activity of the thyroid gland, resulting in retardation of growth and mental development in children and adults
- too much antidiuretic hormone (vasopressin) is released by the pituitary gland
- decrease in the amount of sodium in the blood
- diabetes mellitus
- worsening of pre-existing diabetes
- a condition (called ‘metabolic syndrome’) where you may have a combination of 3 or more of the following: an increase in the fat around your abdomen, a decrease in ‘good cholesterol’ (HDL), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar
- walking, talking, eating or other activities while you are asleep
- unpleasant sensation in the legs (also called restless legs syndrome)
- uncontrollable movements, mainly of your face or tongue
- change in electrical activity of the heart seen on ECG (QT prolongation)
- a slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting

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- stuffy nose
- difficulty swallowing
- severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis)
- bowel obstruction
- increased certain liver functions (AST)
- inflammation of the liver
- breakdown of muscle fibres and pain in muscles (rhabdomyolysis)
- difficulty in passing urine
- a long-lasting and painful erection (priapism)
- swelling of breasts and unexpected production of breast milk (galactorrhoea)
- sexual dysfunction
- menstrual disorders
- body temperature decreased (hypothermia)
- increased blood creatine phosphokinase (a substance from muscles).

*Unknown frequency:*

- skin rash with irregular red spots (erythema multiforme)
- symptoms of withdrawal may occur in new-born babies of mothers that have used QUETIAPINE TEVA during their pregnancy.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction**

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**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 QUETIAPINE TEVA.

**5. HOW TO STORE QUETIAPINE TEVA:**

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep in original packaging till needed for use. Protect from moisture.

Do not use after the expiry date stated on the label/carton/bottle.

Return all unused medicine to your pharmacist.

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

**6. CONTENTS OF THE PACK AND OTHER INFORMATION:****What QUETIAPINE TEVA contains:**

The active substance(s) is QUETIAPINE fumarate.

The other ingredient(s) are:

**Tablet core:** cellulose, microcrystalline, hypromellose (Methocel E5 Premium), hypromellose (Methocel K100 Premium LV), hypromellose (Methocel K4M Premium CR), magnesium stearate, sodium citrate; anhydrous.

**Tablet coating:**

QUETIAPINE 50 Teva: Opadry 15B265003 Brown consisting of HPMC 2910/ hypromellose 3cP, HPMC 2910/ hypromellose 6 cP, iron oxide yellow, iron oxide red, iron oxide black, macrogol/PEG 400, polysorbate 80, titanium dioxide.

QUETIAPINE 200 Teva: Opadry 15B220002 Yellow consisting of HPMC 2910/ hypromellose 3cP, HPMC 2910/ hypromellose 15 cP, iron oxide yellow, iron oxide red, macrogol/PEG 400, polysorbate 80, titanium dioxide.

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QUETIAPINE 300 Teva: Opadry 15B220003 Yellow consisting of HPMC 2910/ hypromellose 3cP, HPMC 2910/ hypromellose 6 cP, iron oxide yellow, iron oxide red, iron oxide black, macrogol/PEG 400, polysorbate 80, titanium dioxide.

QUETIAPINE 400 Teva: Opadry YS-1-7003 White consisting of HPMC 2910/ hypromellose 3cP, HPMC 2910/ hypromellose 6 cP, macrogol/PEG 400, polysorbate 80 titanium dioxide.

**What QUETIAPINE TEVA looks like and contents of the pack:**

QUETIAPINE 50 Teva: Brown, biconvex, oblong, film-coated tablets with debossing 'Q50' on one side.

QUETIAPINE 200 Teva: Yellow, biconvex, oblong, film-coated tablets with debossing 'Q200' on one side.

QUETIAPINE 300 Teva: Light yellow, biconvex, oblong, film-coated tablets with debossing 'Q300' on one side.

QUETIAPINE 400 Teva: White, biconvex, oblong, film-coated tablets with debossing 'Q400' on one side.

QUETIAPINE TEVA film-coated tablets are packed into PVC/Aclar aluminium and PVC/PVDC foil white blisters containing 10, 20, 30, 50, 60, 90 or 100 tablets. Not all pack sizes may be marketed.

White opaque HDPE tablet container with white opaque PP cap integrated with 2 g silica gel desiccant containing 60 tablets.

**Holder of Certificate of Registration:**

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

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Tel: +27 11 055 0200

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