

PACKAGE LEAFLET

QUET 200 mg Film Coated Tablets

Taken by mouth.

Active substance: Each film-coated tablet contains 230.26 mg quetiapine fumarate equal to 200 mg quetiapine.

Excipients: Dibasic calcium phosphate dehydrate, lactose monohydrate (from cow's milk), povidone, sodium starch glycolate, magnesium stearate, colloidal silicon dioxide, microcrystalline cellulose, sodium stearyl fumarate, *Opadry Y-1-7000 White*: HPMC 2910/Hypromellose 5 cp, titanium dioxide, macrogol/PEG 400.

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

- 1. What QUET is and what it is used for***
- 2. What you need to know before you take QUET***
- 3. How to take QUET***
- 4. Possible side effects***
- 5. How to store QUET***

1. WHAT QUET IS AND WHAT IT IS USED FOR

QUET is a white-colored, round-shaped, homogenous-looking, film-coated tablet. QUET 200 mg is offered in packs of 30 or 60 tablets.

Quetiapine, the active substance of QUET, belongs to a group of medicines called antipsychotics (drugs used in the treatment of psychiatric diseases).

QUET is effective in treating the following diseases:

- *Major depressive episodes associated with bipolar disorder:* where you feel sad. You may find yourself depressed, experience guilt, lack of energy, loss of appetite or inability to sleep.
- *Moderate to severe manic episodes in bipolar disorder:* where you may feel very excited, elated, agitated, enthusiastic or hyperactive (needing to sleep less than usual, being more talkative than usual, having racing thoughts or ideas) or have poor judgment including being aggressive or disruptive.
- For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to quetiapine treatment.
- *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.

Your doctor may continue to prescribe QUET even when you are feeling better.



2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE QUET

QUET should not be used by elderly patients with loss of brain function (dementia) that causes impairment of memory and thinking. This is because the group of drugs that QUET belongs to may increase the risk of stroke and, in some cases, of death in elderly patients with dementia.

In clinical studies with quetiapine and other drugs of this group, increased risk of death was reported in elderly patients with dementia and behavioral disorder. QUET is not approved for this type of administration.

The use of antidepressant drugs, especially in children and adolescents up to the age of 24, may increase suicidal thoughts or behaviors. For this reason, your doctor will monitor you closely for unexpected behavioral changes such as restlessness, hyperactivity, or the possibility of suicide, especially at the beginning and first months of your treatment or during the periods of increasing/decreasing your dose or stopping your treatment. Call your doctor as soon as possible if your condition worsens, if you have suicidal thoughts or behavior, or thoughts of harming yourself.

QUET is not recommended for use in patients under 18 years of age.

DO NOT TAKE QUET:

- If you are allergic to the active substance quetiapine or any of the other ingredients of QUET (see the list of “excipients”).
- If you are taking any of the following medicines:
 - Some medicines for HIV (HIV protease inhibitors such as didanosine, lopinavir, ritonavir)
 - Azole medicines used for fungal infections (ketoconazole, fluconazole, itraconazole)
 - Medicines for infections like erythromycin or clarithromycin
 - Some depression medicines such as nefazodone

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

TAKE SPECIAL CARE with QUET:

- 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 or if you are taking any medicines that may have an impact on the way your heart beats.
- If you have low blood pressure.
- If you have had a stroke, especially if you are elderly.
- If you have problems with your liver.
- If you have ever had a fit (seizure).
- If 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 QUET.
- 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). If you are, QUET should not be taken because the group of medicines that QUET belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.
- If you are an elderly person with Parkinson’s disease/parkinsonism.
- If 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.
- If you have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called “sleep apnea”) and are taking medicines that slow down the normal activity of the brain (“depressants”).



- If you have or have 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 “anti-cholinergics”) that affect the way nerve cells function in order to treat certain medical conditions.
- If you have problems in your veins. QUET poses a rare risk of causing venous occlusion. All risk factors should be identified and necessary measures should be taken before and during therapy.
- If you have a history of alcohol or drug abuse.

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

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (this phenomenon is called “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.
- Seizures.
- A long-lasting and painful erection (priapism).
- A rapid and irregular heartbeat, even when you are at rest, as well as palpitations, breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, will refer you to a cardiologist immediately.

These conditions can be caused by this type of medicine.

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 QUET 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.
- **Thoughts of suicide and worsening of your depression**

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 2 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 behavior 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. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behavior.

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 combined with rash, fever, enlarged glands, and abnormal blood test results (including an increase in white blood cell levels (eosinophilia) and an increase in liver enzyme levels)
- Acute Generalized Exanthematous Pustulosis (AGEP) – small pus-filled blisters
- Erythema Multiforme (EM) – skin rash with irregular, red and itchy spots

Stop using QUET immediately if you develop any of these symptoms and tell your doctor or seek immediate medical care.

Weight gain

Weight gain has been observed in patients receiving QUET. You should monitor your weight regularly with your doctor.

Children and adolescents

QUET is not intended for use in children and adolescents below 18 years of age.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Taking QUET with food and drink

- QUET can be taken with or without food.
- Be careful how much alcohol you drink. This is because the combined effect of QUET and alcohol can make you sleepy.
- Do not drink grapefruit juice during treatment with QUET. Grapefruit juice may affect the way the medicine works.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

If you think you are pregnant or planning to become pregnant, tell your doctor before taking QUET. You should not take QUET during pregnancy unless this has been discussed with your doctor.

Newborns of mothers exposed to antipsychotic medicines (effective in treating mental illnesses such as schizophrenia, psychotic depression) in the last 3 months of pregnancy are at risk for abnormal muscle movements and/or drug withdrawal symptoms, which may vary in severity following birth. These symptoms include restlessness, excessive muscle tension, loss of muscle tension, tremors, sleepiness, breathing difficulties or nutritional disorders. If your baby develops any of these symptoms, you must contact your doctor.

If you find out that you are pregnant during your treatment, immediately refer to your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Do not breastfeed your baby while you are using this medicine.

Driving and using machines

The use of this medicine may cause drowsiness. Do not drive or operate machinery until you know how the medicine affects you.

Important information about some excipients of QUET

QUET contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

Taking other medicines

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

- Some medicines used to treat AIDS (HIV) (like HIV-protease inhibitors e.g. didanosine, lopinavir, ritonavir)
- Medicines belonging to azole class used to treat fungal infections (such as ketoconazole, fluconazole, itraconazole)
- Erythromycin or clarithromycin (used to treat infections)
- Medicines used to treat depression e.g. nefazodone

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

- Medicines for epilepsy (like phenytoin or carbamazepine)
- Medicines for high blood pressure
- Barbiturates (for difficulty sleeping)
- Thioridazine or lithium (other antipsychotic medicines)
- 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 used to treat infections)
- Medicines that may cause constipation
- Medicines that affect the function of nerve cells in order to treat certain medical conditions (called “anticholinergics”)

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

If you are currently taking or have recently taken any prescribed or non-prescribed medicines, please inform your doctor or pharmacist about such medicines.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking QUET 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 such a result is obtained, the results may need to be confirmed with more specific tests.

3. HOW TO TAKE QUET

Instructions for proper use and dose/administration frequency

Always take QUET exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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.

Route and method of administration

- You will take your tablets once a day, at bedtime or twice a day, depending on your illness.
- Swallow your tablets whole with some water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while taking QUET. It can affect the way the medicine works.
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.



Different age groups

Use in children and adolescents

QUET should not be used by children and adolescents under 18 years of age.

Use in the elderly

If you are elderly, your doctor may change your dose.

Special conditions for use

Kidney problems

Dose adjustment is not required for patients with kidney problems.

Liver problems

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

If you observe that the effect of QUET is too strong or too weak, consult your doctor or pharmacist.

If you have taken more QUET than you should

If you have taken more QUET than you should, talk to a doctor or pharmacist immediately.

If you take more QUET 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 QUET tablets with you.

If you forget to take QUET

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

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.

If you stop taking QUET

If you suddenly stop taking QUET, you may be unable to sleep (insomnia), or you may feel sick (nausea), or you may experience headache, diarrhea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following occur, stop using QUET and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- A severe allergic reaction which may cause difficulty in breathing or shock (called anaphylaxis)
- Allergic reactions including skin blisters, swelling of the skin and swelling around the mouth
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema)

These are all very serious side effects. If you get any of them, it means you have a serious allergy to QUET. You may need urgent medical attention or hospitalization. These side effects occur rarely.

Side effects are classified in the following frequencies:

Very common	: may affect at least 1 in 10 patients.
Common	: may affect less than 1 in 10 patients, but more than 1 in 100 patients.
Uncommon	: may affect less than 1 in 100 patients, but more than 1 in 1,000 patients.
Rare	: may affect less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
Very rare	: may affect less than 1 in 10,000 patients.
Not known	: cannot be estimated from the available data.

Other side effects of QUET are as follows:

Very common

- Dizziness (may lead to falls), headache, dry mouth.
- Decreased level of hemoglobin
- Feeling sleepy (this may go away with time, as you keep taking QUET) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking QUET) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhea, being sick (vomiting), dizziness and irritability. Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.
- Putting on weight.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Changes in the amount of certain fats (triglycerides and total cholesterol).

Common

- Rapid heartbeat.
- Feeling like your heart is pounding, racing or has skipped beats.
- Constipation, upset stomach (indigestion).
- Feeling weak.
- Swelling of arms or legs.
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Increased levels of sugar in the blood.
- Blurred vision.
- Abnormal dreams and nightmares.
- Feeling hungrier.
- Feeling irritated.
- Disturbance in speech and language.
- Thoughts of suicide and worsening of your depression.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Changes in the amount of thyroid hormones in your blood.
- Decreases in the number of certain types of blood cells.
- Increases in the amount of liver enzymes measured in the blood.
- Increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
 - Men and women to have swelling breasts and unexpectedly produce breast milk.
 - Women to have no monthly periods or irregular periods.

Uncommon

- Fits or seizures.
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Uncontrollable movements, mainly of your face or tongue.
- Sexual dysfunction.
- Diabetes.



- 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.
- Difficulty in passing urine.
- Fainting (may lead to falls).
- Stuffy nose.
- Decrease in the amount of red blood cells.
- Decrease in the amount of sodium in the blood.
- Decrease in the amount of neutrophils, a type of white blood cell
- Worsening of pre-existing diabetes.

Confusional state.

- Decreased thrombocyte count (blood platelets).
- Reduction in blood hormone levels (decreases in free T3, hypothyroidism).
- Elevations in the levels of serum aspartate aminotransferase (AST) (enzyme test often used to diagnose heart and liver diseases).

Rare

- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).
- Yellowing of the skin and eyes (jaundice).
- Inflammation of the liver (hepatitis).
- A long-lasting and painful erection (priapism).
- Swelling of breasts and unexpected production of breast milk (galactorrhea).
- Menstrual disorder.
- 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.
- Walking, talking, eating or other activities while you are asleep.
- Body temperature decreased (hypothermia).
- Inflammation of the pancreas.
- A condition (called “metabolic syndrome”) where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in “good cholesterol” (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.
- Bowel obstruction.
- Increased blood creatine phosphokinase (a substance from the muscles).
- Interruption in breathing for short periods during normal night sleep (sleep apnea).

Very rare

- Severe rash, blisters, or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).
- Inappropriate secretion of a hormone that controls urine volume.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)

Not known

- Skin rash with irregular red spots (erythema multiforme).
- Rapid appearance of areas of red skin dotted 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) 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 newborn babies of mothers that have used quetiapine during their pregnancy.
- Stroke.
- 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.

The class of medicines to which QUET belongs can cause heart rhythm problems, which can be serious and in severe cases may be fatal.

Some side effects are only seen when a blood test is taken. These include changes in the amount of certain fats (triglycerides and total cholesterol) or sugar in the blood, changes in the amount of thyroid hormones in your blood, increased liver enzymes, decreases in the number of certain types of blood cells, decrease in the amount of red blood cells, increased blood creatine phosphokinase (a substance in the muscles), decrease in the amount of sodium in the blood and increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:

- Men and women to have swelling of breasts and unexpectedly produce breast milk
- Women to have no monthly period or irregular periods

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

- Increase in the amount of a hormone called prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
 - 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.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Increase in blood pressure.

Common

- Feeling weak, fainting (may lead to falls).
- Stuffy nose.
- Feeling irritated.



Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE QUET

Keep QUET out of reach and sight of children and in its original package.

Store QUET at room temperature below 25°C.

Take this medicine in accordance with expiry date.

Do not use QUET after the expiry date which is stated on the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder

DEVA Holding A.Ş.

Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing site

DEVA Holding A.Ş.

Kapaklı – TEKİRDAĞ / TÜRKİYE

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