

Package leaflet: Information for the patient

Quetex 100 mg film-coated tablets
Quetex 200 mg film-coated tablets
Quetex 300 mg film-coated tablets

quetiapine

Read all of this 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Quetex is and what it is used for
2. What you need to know before you take Quetex
3. How to take Quetex
4. Possible side effects
5. How to store Quetex
6. Contents of the pack and other information

1. What Quetex is and what it is used for

Quetex contains the active substance quetiapine. This belongs to a group of medicines called antipsychotics. Quetex 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.
- 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.

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

2. What you need to know before you take Quetex

Do not take Quetex

- If you are allergic to quetiapine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking any of the following medicines:
 - some medicines used to treat HIV infections
 - azole medicines (medicines used to treat fungal infections)
 - erythromycin or clarithromycin (medicines used to treat bacterial infections)
 - nefazodone (medicine used to treat depression).

Do not take Quetex if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Quetex.

Warnings and precautions

Talk to your doctor or pharmacist before taking Quetex:

- 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 Quetex.
- 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, Quetex should not be taken because the group of medicines that Quetex 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 apnoea") and are taking medicines that slow down the normal activity of the brain ("depressants")
- 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 have a history of alcohol or drug abuse.

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

- 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.
- 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.
- Fits (seizures)
- A long lasting and painful erection (priapism)
- Have a fast and irregular heartbeat even when you are at rest (palpitations), breathing problems, chest pain or unexplained tiredness. Your doctor will need to check your heart and if necessary, 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 Quetex 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 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. 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.

Weight gain

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

Children and adolescents

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

Other medicines and Quetex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- Some medicines used to treat HIV infections.
- Azole medicines (medicines used to treat fungal infections).
- Erythromycin or clarithromycin (medicines used to treat bacterial infections).
- Nefazodone (medicine used to treat depression).

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

- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (medicines used to treat difficulty sleeping).
- Thioridazine or lithium (other anti-psychotic 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 (medicines used to treat bacterial infections).
- Medicines that can cause constipation.
- Medicines (called “anti-cholinergics”) that affect the way nerve cells function in order to treat certain medical conditions.

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

Quetex with food, drink and alcohol

- Food: see section 3 under “Method of administration”.
- Be careful how much alcohol you drink. This is because the combined effect of Quetex and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are taking Quetex. It can affect the way the medicine works.

Pregnancy and breast-feeding

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Quetex during pregnancy unless this has been discussed with your doctor. The following symptoms which can represent withdrawal may occur in newborn babies, of mothers who have used Quetex 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.

Quetex should not be taken if you are breast-feeding.

Driving and using machines

Your tablets may make you feel sleepy and dizzy. Do not drive or use any tools or machines until you know how the tablets affect you.

Effect on urine drug screens

If you are having a urine drug screen, taking Quetex 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.

Quetex contains sodium, lactose

This medicine contains less than 1 mmol sodium (23 mg) film-coated tablet, that is to say essentially 'sodium-free'.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Quetex

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

Medicinal products containing lower strengths of quetiapine are available for doses not realizable/practicable with this medicine.

The recommended dose is:

Adults

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, at bedtime or twice a day, depending on your illness

Elderly people

If you are elderly your doctor may change your dose.

Liver problems

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

Use in children and adolescents

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

Method of administration

For oral use.

- *Quetex 300 mg film-coated tablets*
The tablet can be divided into two equal doses. If required, place it on a hard surface with the notched side facing up. Then press the tablet using your thumbs at both ends at the same time.
- *Quetex 100 mg film-coated tablets*
Quetex 200 mg film-coated tablets
The tablet can be divided into four equal doses. If required, place it on a hard surface with the notched side facing up. Then press the tablet in the middle with your thumb.
- Swallow your tablets with a drink of water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while you are taking Quetex. It can affect the way the medicine works.

Duration of treatment:

This will be decided by your doctor. Do not stop taking your tablets even if you feel better, unless your doctor tells you.

If you take more Quetex than you should

If you take more Quetex 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 tablets with you.

If you forget to take Quetex

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 stop taking Quetex

If you suddenly stop taking Quetex, 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.

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.

Stop taking Quetex immediately and contact your doctor at once or go to the nearest hospital if you experience any of the following serious side effects:

Uncommon side effects, may affect up to 1 in 100 people:

- fits or seizures
- uncontrollable movements, mainly of your face or tongue.

Rare side effects, may affect up to 1 in 1,000 people:

- combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”)
- long-lasting and painful erection (priapism)
- 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
- combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count (a condition called agranulocytosis).

Very rare side effects, may affect up to 1 in 10,000 people:

- a serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- severe allergic reaction (anaphylaxis), which may cause difficulty in breathing or shock
- rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).

Not known, frequency of these side effects cannot be estimated from the available data:

- serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis)
- skin rash with irregular red spots (erythema multiforme)
- 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). Stop using Quetex if you develop these symptoms and contact your doctor or seek medical attention immediately.

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

You may experience any of the other reported side effects listed below according to the frequencies:

Very common, may affect more than 1 in 10 people:

- dizziness (may lead to falls), headache, dry mouth
- feeling sleepy (this may go away with time, as you keep taking Quetex (may lead to falls)
- discontinuation symptoms (symptoms which occur when you stop taking Quetex) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, 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, may affect up to 1 in 10 people:

- 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 more hungry
- 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 of breasts and unexpectedly produce breast milk
 - women to have no monthly period or irregular periods.

Uncommon, may affect up to 1 in 100 people:

- 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
- 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
- worsening of pre-existing diabetes.

Rare, may affect up to 1 in 1,000 people:

- yellowing of the skin and eyes (jaundice)
- inflammation of the liver (hepatitis)
- swelling of breasts and unexpected production of breast milk (galactorrhoea)
- menstrual disorder
- 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 three 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
- bowel obstruction
- increased blood creatine phosphokinase (a substance from the muscles).

Very rare, may affect up to 1 in 10,000 people:

- severe rash, blisters, or red patches on the skin
- inappropriate secretion of a hormone that controls urine volume
- breakdown of muscle fibers and pain in muscles (rhabdomyolysis).

Not known, frequency cannot be estimated from the available data

- symptoms of withdrawal may occur in newborn babies of mothers who have used Quetex 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.

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.

Your doctor may ask you to have blood tests from time to time.

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, may affect more than 1 in 10 people:

- increase in the amount of a hormone called prolactin in the blood
This 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, may affect up to 1 in 10 people:

- feeling weak
- fainting (may lead to falls)
- stuffy nose
- feeling irritated.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Quetex

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

Shelf life after first opening of the bottle:

Do not use after 6 months have elapsed from first opening.

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.

6. Contents of the pack and other information

What Quetex contains

The active substance is quetiapine (as fumarate).

Each film-coated tablet contains 100 mg of quetiapine (as fumarate).

Each film-coated tablet contains 200 mg of quetiapine (as fumarate).

Each film-coated tablet contains 300 mg of quetiapine (as fumarate).

The other ingredients are:

Tablet core: calcium hydrogen phosphate dihydrate, microcrystalline cellulose, lactose monohydrate, magnesium stearate, povidone (K29/32), silica colloidal hydrated, sodium starch glycolate (type A);

Tablet coating: hypromellose, lactose monohydrate, macrogol 4000, titanium dioxide (E171), iron oxide yellow (E172) (for 100 mg).

What Quetex looks like and contents of the pack

100 mg film-coated tablets:

The film-coated tablets are yellow and round (approx. 8.8 mm diameter) with score line on one side.

200 mg film-coated tablets:

The film-coated tablets are white and round (approx. 11.5 mm diameter) with score line on one side.

300 mg film-coated tablets:

The film-coated tablets are white and oval (approx. 18 mm length and 8.8 mm width) with score line on both sides.

The film-coated tablets are packed in PVC/COC/PVDC/ALU, PVC/PVDC/Aluminium or PVC/PE/PVDC/Aluminium blister and inserted in a carton or packed in HDPE-bottle with PP or PE screw caps with desiccant (silica gel).

Pack sizes:

100 mg, 200 mg and 300 mg film-coated tablets:

Blister 6, 10, 20, 30, 50, 60, 90, 100, 100x1 [perforated unit dose blister], or 120 film-coated tablets

Bottle: 100, 250 or 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

LEK S.A., Ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

S.C. Sandoz S.R.L., 7A Livezeni Street, 540472 Targu Mures, Jud. Mures, Romania.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Seresano

Germany: Quetiapin HEXAL 100 mg Filmtabletten
Quetiapin HEXAL 200 mg Filmtabletten
Quetiapin HEXAL 300 mg Filmtabletten

Ireland: Quetex 100 mg film-coated tablets
Quetex 200 mg film-coated tablets
Quetex 300 mg film-coated tablets

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