

## Package leaflet: Information for the user

Quetiapine Fairmed Healthcare 50 mg tabletten met verlengde afgifte  
Quetiapine Fairmed Healthcare 150 mg tabletten met verlengde afgifte  
Quetiapine Fairmed Healthcare 200 mg tabletten met verlengde afgifte  
Quetiapine Fairmed Healthcare 300 mg tabletten met verlengde afgifte  
Quetiapine Fairmed Healthcare 400 mg tabletten met verlengde afgifte

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

#### 1. What <Product name> is and what it is used for

<Product name> contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics. <Product name> 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 and/or have poor judgment including being aggressive or disruptive.
- Bipolar depression and major depressive episodes in major depressive disorder: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or have sleep issues.

When <Product name> is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another drug being used to treat this illness.

You must talk to a doctor if you do not feel better or if you feel worse.

#### 2. What you need to know before you take <Product name>

**Do not take <Product name>:**

- 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 for 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 <Product name>.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking <Product name> if you:

- or someone in your family ever 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.
- have low blood pressure.
- have had a stroke, especially if you are elderly.
- have liver problems.
- have ever had a fit (seizure).
- have diabetes or are at risk of developing diabetes, your doctor may check your blood sugar levels while you are taking <Product name>.
- had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- are an elderly person with dementia (loss of brain function). If you are, <Product name> should not be taken because this type of medicines may increase the risk of stroke, or in some cases the risk of death.
- are an elderly person with Parkinson's disease/parkinsonism.
- or someone in your family has a history of blood clots, as medicines like these have been associated with blood clot formation.
- have ever had a condition where you stop breathing for short periods while asleep (sleep apnoea) and are taking medicines that slow down the normal activity of the brain (depressants).
- have ever 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 (anticholinergics) that affect the way nerve cells function in order to treat certain medical conditions.
- have a history of alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking <Product name>:

- 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 feeling extremely sleepy. This could increase the risk of accidental injury 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 (see section 4).

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 <Product name> 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.

### **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 <quetiapine> if you develop these symptoms and contact your doctor or seek medical attention immediately.

### **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)

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

**Weight gain**

Weight gain has been seen in patients taking <Product name>. You and your doctor should check your weight regularly.

**Children and adolescents**

<Product name> is not for use in children and adolescents below 18 years of age.

**Other medicines and <Product name>**

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

Do not take <Product name> 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)

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

- epilepsy medicines (like phenytoin or carbamazepine)
- high blood pressure medicines
- barbiturates (for 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 (drugs to treat infections)
- medicines that can cause constipation
- medicines (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 first.

**<Product name> with food, drink and alcohol**

- <Product name> can be affected by food and you should therefore take your tablets at least one hour before a meal or just before bedtime.
- Be careful how much alcohol you drink - the combined effect of <Product name> and alcohol can make you sleepy.
- Do not drink grapefruit juice or eat grapefruit while you are taking <Product name> - 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 for advice before taking this medicine.

You should not take <Product name> during pregnancy unless this has been discussed with your doctor. <Product name> should not be taken if you are breast-feeding.

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

### **Driving and using machines**

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

### **<Product name> contains lactose and sodium.**

<Product name> 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.

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

### **Effect on Urine Drug Screens**

If you have a urine drug screen, taking <Product name> may cause positive results for methadone or certain drugs for depression called tricyclic antidepressants (TCAs), even though you are not taking methadone or TCAs. If this happens, a more specific test can be performed.

## **3. How to take <Product name>**

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

### Dosage

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

### Method of administration

- Take your tablets once a day.
- Swallow your tablets whole with a drink of water.
- Take your tablets without food (at least one hour before a meal or at bedtime, your doctor will tell you when is best).
- Do not drink grapefruit juice or eat grapefruit while you are taking <Product name>. It can affect the way the medicine works.
- Do not stop taking your tablets even if you feel better unless your doctor tells you.
- Do not split, chew on or crush your tablet.

### **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.

### **If you take more <Product name> than you should**

If you take more <Product name> than prescribed by your doctor, you may feel sleepy, dizzy and experience abnormal heart beats. Contact your doctor or nearest hospital straight away. Keep the <Product name> tablets with you.

### **If you forget to take <Product name>**

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 <Product name>**

If you suddenly stop taking <Product name>, you may be unable to sleep (insomnia), feel sick (nausea), or 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.

**Very common (may affect more than 1 in 10 people):**

- dizziness (may lead to falls), headache, dry mouth. Tell your doctor immediately.
- feeling sleepy (this may go away, the longer you keep taking <Product name>) (may lead to falls). Tell your doctor immediately.
- discontinuation symptoms (symptoms which occur when you stop taking <Product name>) including 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 to move, shaking, feeling restless or muscle stiffness without pain. Tell your doctor immediately.
- changes in the levels of certain blood fats (triglycerides and 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
- swollen arms or legs
- low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls)
- increased blood sugar levels
- blurred vision
- abnormal dreams and nightmares
- feeling hungrier than usual
- 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 levels of thyroid hormones in your blood
- decreased number of certain types of blood cells
- increased levels of liver enzymes measured in the blood

- increased levels of the hormone prolactin in the blood. This could in rare cases lead to the following:
  - swelling of the breasts and unexpected production of breast milk in both men and women
  - no monthly period or irregular periods

**Uncommon (may affect up to 1 in 100 people):**

- fits or seizures. Tell your doctor immediately.
- 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 the electrical activity of the heart as seen on an 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 passing urine
- fainting (may lead to falls)
- stuffy nose
- decreased red blood cell count
- decreased levels of sodium in the blood
- worsening of pre-existing diabetes

**Rare (may affect up to 1 in 1,000 people):**

- a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called neuroleptic malignant syndrome) Tell your doctor immediately.
- yellowing of the skin and eyes (jaundice)
- inflammation of the liver (hepatitis)
- a long-lasting and painful erection (priapism). Tell your doctor immediately.
- swelling of breasts and unexpected production of breast milk (galactorrhoea)
- 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 breathing. If you notice any of these symptoms seek medical advice immediately
- walking, talking, eating or other activities while you are asleep
- decreased body temperature (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)

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

- severe rash, blisters, or red patches on the skin
- a severe allergic reaction (anaphylaxis) which may cause difficulty 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). See section 2.
- abnormal secretion of a hormone that controls urine volume
- breakdown of muscle fibers and muscle pain (rhabdomyolysis)

**Not known (frequency cannot be estimated from the available data):**

- skin rash with irregular red spots (erythema multiforme)
- serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis). See section 2.
- symptoms of withdrawal in newborn babies of mothers that have used <Product name> during their pregnancy
- stroke
- 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). See section 2.
- 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 <Product name> 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.

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

**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 (may affect more than 1 in 10 people):**

- increased levels of the hormone prolactin in the blood. This could in rare cases lead to the following:
  - swelling of the breasts and unexpected production of breast milk in both boys and girls



- no monthly period or irregular periods
- increased appetite
- vomiting
- abnormal muscle movements. These include difficulty starting to move, 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 <To be completed nationally>**. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store <Product name>**

This medicine does not require any special storage conditions.

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 after EXP. The expiry date refers to the last day of that month.

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 <Product name> contains**

- The active substance is quetiapine.
- Each 50 mg tablet contains 50 mg quetiapine (as quetiapine fumarate)
- Each 150 mg tablet contains 150 mg quetiapine (as quetiapine fumarate)
- Each 200 mg tablet contains 200 mg quetiapine (as quetiapine fumarate)
- Each 300 mg tablet contains 300 mg quetiapine (as quetiapine fumarate)
- Each 400 mg tablet contains 400 mg quetiapine (as quetiapine fumarate)

The other ingredients are:

Tablet core: lactose monohydrate, hypromellose, sodium chloride, povidone K-30, talc and magnesium stearate (E470b). The 50 mg tablet also contains silicified microcrystalline cellulose. The 150 mg tablet also contains microcrystalline cellulose.

**Tablet coating:** titanium dioxide (E171), macrogol (E1521). The 50 mg and 150 mg tablets also contain poly (vinyl alcohol) (E1203), talc (E553b). The 50 mg also contains iron oxide red (E172). The 50 mg, 200 mg and 300 mg also contain iron oxide yellow (E172). The 200 mg, 300 mg and 400 mg also contain hypromellose (E464).

**What <Product name> looks like and contents of the pack**

**50 mg:**

Peach colored, round shaped, biconvex film coated tablets, debossed with 'Q50' on one side and plain on the other.

**150 mg:**

White to off white, capsule shaped, biconvex, film coated tablets, debossed with 'AB2' on one side and plain on other side.

**200 mg:**

Yellow colored, round shaped, biconvex film coated tablets, debossed with 'I2' on one side and plain on the other.

**300 mg:**

Light yellow colored, round shaped, biconvex film coated tablets, debossed with 'Q300' on one side and plain on the other.

**400 mg:**

White colored, round shaped, biconvex, film coated tablets debossed with 'I4' on one side and plain on the other.

Alu-alu blister pack sizes:

50 mg: 10, 50, 100 prolonged-release tablets

150 mg: 10, 50, 100 prolonged-release tablets

PVC/PVdC-Alu blister pack sizes:

50 mg: 10, 50, 100 prolonged-release tablets

150 mg: 10, 50, 100 prolonged-release tablets

200 mg: 10, 50, 100 prolonged-release tablets

300 mg: 10, 50, 100 prolonged-release tablets

400 mg: 10, 50, 100 prolonged-release tablets

HDPE container:

150 mg: 60, 100 prolonged release tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Vergunninghouder:**

Fairmed Healthcare GmbH

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22301 Hamburg

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**Fabrikant:**

Fairmed Healthcare GmbH

Maria-Goeppert-Straße 3  
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Duitsland

**In het register ingeschreven onder:**

Quetiapine Fairmed Healthcare 50 mg tabletten met verlengde afgifte	RVG 127245
Quetiapine Fairmed Healthcare 200 mg tabletten met verlengde afgifte	RVG 127246
Quetiapine Fairmed Healthcare 300 mg tabletten met verlengde afgifte	RVG 127247
Quetiapine Fairmed Healthcare 400 mg tabletten met verlengde afgifte	RVG 127248
Quetiapine Fairmed Healthcare 150 mg tabletten met verlengde afgifte	RVG 127249

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Nederland	Quetiapine Farimed Healthcare 50 mg, 150 mg, 200 mg, 300 mg, 400 mg tabletten met verlengde afgifte
Oostenrijk	Quetiapin Fairmed Healthcare 50 mg, 150 mg, 200 mg, 300 mg, 400 mg Retardtabletten
Duitsland	Quetiapin Fairmed Healthcare 50 mg, 150 mg, 200 mg, 300 mg, 400 mg Retardtabletten

**Deze bijsluiter is voor het laatst goedgekeurd in oktober 2021.**