

PACKAGE LEAFLET: INFORMATION FOR THE USER

Quetiapine Arrow 25mg Film-coated Tablets
Quetiapine Arrow 100mg Film-coated Tablets
Quetiapine Arrow 150mg Film-coated Tablets
Quetiapine Arrow 200mg Film-coated Tablets
Quetiapine Arrow 300mg Film-coated Tablets

(Quetiapine)

Read all of this leaflet carefully before you start taking this medicine.

- 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. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Quetiapine Arrow Tablets are and what they are used for
2. Before you take Quetiapine Arrow Tablets
3. How to take Quetiapine Arrow Tablets
4. Possible side effects
5. How to store Quetiapine Arrow Tablets
6. Further information.

1. WHAT QUETIAPINE ARROW TABLETS ARE AND WHAT THEY ARE USED FOR

Quetiapine belongs to a group of medicines called antipsychotics. These medicines help with conditions that cause symptoms such as:

- Hallucinations (like hearing unexplained voices), strange and frightening thoughts, changes in how you act, and feeling alone and confused. This is also known as schizophrenia.
- Effects on your mood and feeling very “high” or excited. You may find that you need to sleep less than usual. You may also be more talkative and have racing thoughts or ideas. You may also feel more irritable than usual. This is also known as bipolar mania.
- Effects on your mood whereby you feel sad all the time. You may find that you feel depressed, feel guilty, lack energy, lose your appetite and/or can’t sleep. This is also known as bipolar depression.

2. BEFORE YOU TAKE QUETIAPINE ARROW TABLETS

Do NOT take Quetiapine Arrow Tablets

- If you are allergic (hypersensitive) to quetiapine or any of the other ingredients in this medicine (see section 6 “Further information”).
- If you are taking any of the following medicines (see “taking other medicines”):
 - certain medicines for the treatment of HIV (AIDS)
 - certain medicines for the treating fungal infections e.g. ketoconazole or itraconazole
 - the antibiotics erythromycin or clarithromycin
 - nefazodone (for depression).

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

Take special care with Quetiapine Arrow Tablets

Quetiapine should not be taken by elderly people with dementia (loss of brain function).

This is because the group of medicines that quetiapine belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia.

Before you take your medicine, tell your doctor if:

- you, or someone in your family have any heart problems, for example heart rhythm problems
- you have low blood pressure
- you have had a stroke, especially if you are elderly
- you have problems with your liver
- you have ever had a fit (seizure)
- 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
- 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 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).

Tell your doctor if you experience:

- A high temperature (fever), stiff muscles, feeling confused
- uncontrollable movements, mainly of your face or tongue
- a feeling of severe sleepiness.

These conditions can be caused by this type of medicine.

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. 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.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines because it may affect the way the medicine work. This includes medicines that you buy without a prescription and herbal medicines.

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

- epilepsy medicines (like phenytoin or carbamazepine)
- high blood pressure medicines such as hydrochlorothiazide
- barbiturates (for difficulty sleeping).
- thioridazine (another anti-psychotic medicine)
- medicines which act on the central nervous system.

- Medicines which may cause certain cardiac disorders such as:
 - o other antipsychotics, used to treat mental disorders
 - o those used to treat irregular heartbeats in class IA or III
 - o antibiotics used to treat bacterial infections
 - o medicines to treat malaria.

- Medicines which influence hepatic enzymes such as;
 - o rifampicin: a medicine to treat tuberculosis or certain other infections
 - o barbiturates: medicines to treat sleeplessness.

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

Taking Quetiapine Arrow Tablets with food and drink

- Quetiapine can be taken with or without food.
- Be careful how much alcohol you drink. This is because the combined effect of quetiapine and alcohol can make you sleepy.
- Do not drink grapefruit juice while you are on quetiapine treatment. It can affect the way the medicine works.

Pregnancy and breast-feeding

If you are pregnant, trying to get pregnant, or breast-feeding, talk to your doctor before taking quetiapine. You should not take quetiapine during pregnancy unless this has been discussed with your doctor. Quetiapine should not be taken if you are breast-feeding.

The following symptoms may occur in newborn babies, of mothers that have used Quetiapine Arrow Tablets 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.

Driving and using machines

If you feel drowsy after taking this medicine, do not drive or operate any tools or machines. Tell your doctor.

Important information about some of the ingredients of Quetiapine Arrow Tablets

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Quetiapine Arrow 25mg Tablets contains Sunset Yellow (E110) and Allura Red (E129) which may cause allergic reactions.

Quetiapine Arrow 150mg Tablets contain Allura Red (E129) which may cause allergic reactions.

3. HOW TO TAKE QUETIAPINE ARROW TABLETS

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

- You will take your tablets once a day, at bedtime or twice a day, depending on your illness
- Swallow your tablets whole with a glass of water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while you are taking quetiapine. It can affect the way the medicine works.

Adults

Schizophrenia

The usual starting dose is 50 mg daily. You will take an increasing number of tablets for the first 4 days of treatment. From day 4 onwards the dose may be increased further, depending on how you respond to the treatment. Your doctor will tell you how many tablets you should take each day. The usual effective dose is between 300 mg and 450 mg daily. The maximum daily dose is 750 mg daily.

Manic episodes associated with bipolar disorder

The usual starting dose is 100 mg daily. You will take an increasing number of tablets for the first 4 days of treatment. From day 4 onwards the dose may be increased further, depending on how you respond to the treatment. Your doctor will tell you how many tablets you should take each day. The usual effective dose is between 400 mg and 800 mg daily. The maximum daily dose is 800 mg daily.

Depressive episodes associated with bipolar disorder

The usual starting dose is 50 mg daily. You will take an increasing number of tablets for the first 4 days of treatment. The recommended daily dose is 300 mg. Take your tablets once daily at bedtime. Your doctor will tell you how many tablets you should take each day.

Children or adolescents under 18 years should not take this medicine.

If you take more Quetiapine Arrow Tablets than you should

You may get the following symptoms:

- drowsiness and feeling sleepy,
- rapid heartbeat and low blood pressure.

Contact your doctor or nearest hospital casualty department immediately. Remember to take the pack and any remaining tablets with you.

If you forget to take Quetiapine Arrow Tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for the one you have missed.

If you stop taking Quetiapine Arrow Tablets

Do not suddenly stop taking this medicine without talking to your doctor first, even if you feel better, as you might experience withdrawal symptoms such as feeling sick, being sick and being unable to sleep.

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Quetiapine Arrow Tablets can cause side effects, although not everybody gets them.

Very common (affects more than 1 patient in 10):

- Dizziness, headache, dry mouth
- feeling sleepy (this may go away with time, as you keep taking quetiapine).
- increased values for fats called triglycerides and total cholesterol (predominantly LDL cholesterol) in the blood
- discontinuation symptoms (symptoms which occur when you stop taking quetiapine) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness, and irritability. They usually go away after 1 week from your last dose
- weight gain, mainly in the first weeks of treatment.

Common (affects 1 to 10 patients in 100):

- Rapid heartbeat
- stuffy nose.
- constipation, upset stomach (indigestion)
- feeling weak, fainting
- decrease in the total number of white blood cells. This may occur after therapy has ended. It is temporary and not severe
- swelling of arms or legs
- low blood pressure when standing up. This may make you feel dizzy or faint
- increased levels of sugar in the blood
- blurred vision
- abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain
- temporary increase of the liver enzymes called ALT and AST in the blood
- decrease in the number of certain blood cells called neutrophilic granulocytes
- increase in the amount of a hormone called prolactin in the blood. This can 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
- abnormal dreams and nightmares
- increased appetite
- feeling irritated

Uncommon (affects 1 to 10 patients in 1,000):

- Increase in the number of certain blood cells called eosinophilic granulocytes
- decrease in the number of certain blood cells called thrombocytes and platelets
- fits or seizures
- allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth

- temporary increase of the liver enzyme called gamma-GT in the blood
- unpleasant sensations in the legs (also called restless legs syndrome)
- difficulty swallowing
- disturbance in speech and language.

Rare (affects 1 to 10 patients in 10,000):

- A high temperature (fever), long lasting sore throat or mouth ulcers, faster breathing, sweating, stiff muscles, feeling very drowsy or faint
- yellowing of the skin and eyes (jaundice)
- a long-lasting and painful erection (priapism)
- increase of an enzyme called creatine phosphokinase in the blood
- swelling of breasts and unexpected production of breast milk (galactorrhoea).

Very rare (affects less than 1 patient in 10,000):

- Worsening of pre-existing diabetes
- uncontrollable movements, mainly of your face or tongue
- inflammation of the liver (hepatitis)
- 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).

Also reported are:

- Small decrease in the blood levels of specific hormones produced by the thyroid gland
- 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
- heart arrest, specific heart rhythm disorders, which can be serious and in severe cases may be fatal.

These occurred with the entire group of medicines called antipsychotics and not with quetiapine in particular.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE QUETIAPINE ARROW TABLETS

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

Do not use Quetiapine Arrow Tablets after the expiry date which is stated on the outer carton after Exp. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Quetiapine Arrow Tablets contain

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PIL

Quetiapine Arrow Tablets contain 25mg, 100mg, 150mg, 200mg or 300mg of quetiapine (as quetiapine fumarate).

The other ingredients are:

Tablet core: cellulose, microcrystalline, calcium hydrogen phosphate dihydrate, sodium starch glycolate (Type A), povidone, lactose monohydrate and magnesium stearate.

Tablet coating:

25mg Tablets: polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), macrogol, talc, sunset yellow (E110), allura red (E129) and indigo carmine (E132).

100mg Tablets: polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), macrogol, talc and iron oxide yellow (E172).

150mg Tablets: polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), indigo carmine (E132), and allura red (E129).

200mg and 300mg Tablets: polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), macrogol and talc.

What Quetiapine Tablets look like and contents of the pack

Film-coated Tablet.

Quetiapine Arrow 25 mg Tablets:

Peach, round, biconvex tablet with 'QT' on one side and 'D' on the other side.

Quetiapine Arrow 100 mg Tablets:

Yellow, round, biconvex tablet with 'QT' over '100' on one side and 'D' on the other side.

Quetiapine Arrow 150 mg Tablets:

Pale yellow, round, biconvex tablet with 'QT' over '150' on one side and 'D' on the other side.

Quetiapine Arrow 200 mg Tablets:

White to off white, round, biconvex tablet with 'QT' over '200' on one side and 'D' on the other side.

Quetiapine Arrow 300 mg Tablets:

White to off-white, capsule-shaped, biconvex tablet with 'QT' over '300' on one side and 'D' on the other side.

Quetiapine Arrow Tablets are packed in foil blister packs containing 6, 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 and 100 (5 x 20) tablets per carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Herts, United Kingdom, SG 1 4SZ

Manufacturer:

Arrow Pharm (Malta) Limited, 62 Hal Far Industrial Estate, Birzebbugia BBG 3000, Malta

Juta Pharma GmbH, Gutenbergstrasse 13, 24941, Flensburg, Germany

Medicofarma S.A., ul. Kozińska 97, 26-600 Radom, Poland

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

TERRITORY	PROPOSED TRADE NAME
Belgium	Quetiapine Arrow Generics 25, 100, 150, 200 and 300mg flimomhulde tabletten
Cyprus	Quetiapine Arrow 25, 100, 150, 200 and 300mg Film-coated tablets
Czech Republic	Quetiapine Arrow 25, 100, 150, 200 and 300mg
Germany	Quetiapin-Q 25, 100, 150, 200 and 300 mg Filmtabletten
Denmark	Quetiapin Arrow 25, 100, 150, 200 and 300mg
Finland	Quetiapin Arrow 25, 100, 150, 200 and 300mg
Hungary	Quetiapine Arrow 25, 100, 150, 200 and 300mg
Ireland	Quetiapine Arrow 25, 100, 150, 200 and 300mg Film-coated Tablets
Malta	Quetiapine 25, 100, 150, 200 and 300mg Film-coated Tablets
Norway	Quetiapin Arrow 25, 100, 150, 200 and 300mg
The Netherlands	Quetiapine Arrow 25, 100, 150, 200 and 300mg
Poland	Quetiapine Arrow
Portugal	Quetiapina arrowblue
Slovenia	Kvetiapin Arrow 25, 100, 150, 200 and 300mg filmsko obložene tablete
Slovakia	Quetiapine Arrow 25, 100, 150, 200 and 300mg
Spain	Quetiapina Arrow 25, 100, 150, 200 and 300mg comprimidos recubiertos con película EFG
Sweden	Quetiapin Arrow 25, 100, 150, 200 and 300mg
United Kingdom	Quetiapine 25, 100, 150, 200 and 300mg Film-coated Tablets

This leaflet was last revised in December 2012