Medication Guide
Quetiapine Tablets

Read this Medication Guide before you start taking quetiapine tablets and each time you get a refill. There may be new information about your medicine. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about quetiapine tablets?
Quetiapine tablets can cause serious side effects, including:

- stroke that can lead to death in elderly people with dementia who take medicines like quetiapine tablets.

- neuroleptic malignant syndrome (NMS). NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including quetiapine tablets. NMS can cause changes in body temperature, blood pressure, and kidney function. This condition should be treated in a hospital. Call your healthcare provider right away if you become severely ill and have some or all of these symptoms:
  - high fever
  - excessive sweating
  - rigid muscles
  - confusion
  - changes in your breathing, heartbeat, and blood pressure.

- falls: can happen in people who take quetiapine tablets. These falls may cause serious injuries.

- high blood sugar (hyperglycemia). High blood sugar can happen if you have diabetes already or if you have never had diabetes. High blood sugar could lead to:
  - build-up of acid in your blood due to ketones (ketoadiposis)
  - coma
  - death

- increased in blood sugar can happen in some people who take quetiapine tablets. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your healthcare provider should check your blood sugar before you start taking quetiapine tablets and during therapy.

Call your healthcare provider if you have any of these symptoms of high blood sugar (hyperglycemia).

What is quetiapine tablet?
Quetiapine tablet is a prescription medicine used to treat:

- certain mental or mood disorders in adults, including:
  - bipolar disorder in adults
  - schizoaffective disorder in adults
  - schizoaffective disorder in children

- mental disorders in children, adolescents, and adults, including:
  - agitation associated with manic episodes associated with bipolar I disorder alone or with lithium or divalproex
  - agitation associated with bipolar I disorder in children ages 10 to 17 years old

Quetiapine tablets can cause serious side effects, including:

- sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities
- increased body temperature
- difficulty swallowing
- trouble sleeping or trouble staying asleep (insomnia), nausea, or vomiting if you suddenly stop taking quetiapine tablets. These symptoms usually get better 1 week after you start having them.

The most common side effects of quetiapine tablets include:

In Adults:

- drowsiness
- sudden drop in blood pressure upon standing
- weight gain
- dry mouth
- dizziness
- weakness
- abdominal pain
- constipation
- sore throat
- weight gain
- increased appetite
- vomiting
- rapid heartbeat

- these are not all the possible side effects of quetiapine tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store quetiapine tablets?

- Store quetiapine tablets at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep quetiapine tablets and all medicines out of the reach of children.

General information about the safe and effective use of quetiapine tablets

Medicines are sometimes prescribed for other purposes or under different names in a Medication Guide. Do not use quetiapine tablets for a condition for which it was not prescribed. Do not give quetiapine tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about quetiapine tablets. If you could have more questions, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about quetiapine tablets that is written for health professionals. For more information, call 1-800-205-7821.

What are the ingredients in quetiapine tablets?

Active ingredient: quetiapine fumarate

Other ingredients in quetiapine tablets include:

- active ingredient, quetiapine fumarate
- dicalcium phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate, lactose monohydrate, magnesium stearate, hydroxypropyl cellulose, polyethylene glycol, and titanium dioxide. The 25 mg tablets contain iron oxide red and yellow.

Actual manufacturer of product:

Intas Pharmaceuticals Limited, Plot No. 5 to 14, Pharmac, Sanjeev Bafna, National Highway 8-A, Near Village Nandgaon, Tal Sanand, Ahmedabad - 382 213, Gujarat, INDIA

Mfg. Lic. No.: G25/1883
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Revised January 2019