

APO-QUETIAPINE TABLETS

Quetiapine Fumarate (25mg, 100mg, 200mg)

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What Apo-Quetiapine is used for

APO-QUETIAPINE is a prescription medication containing the active ingredient, quetiapine fumarate. APO-QUETIAPINE is intended for the relief of depressive episodes associated with the bipolar disorder (an illness marked by extreme shifts in mood). This medication can also be used for the treatment of acute manic episodes associated with the bipolar I disorder, and also schizophrenia.

How Apo-Quetiapine works

APO-QUETIAPINE is an atypical antipsychotic agent. It works by maintaining the amount of certain natural substances in the brain that are needed to maintain mental balance.

Before you use Apo-Quetiapine

- When you must not use it

If you are allergic to quetiapine fumarate, or any ingredients of this medication.

- Before you start to use it

Before taking APO-QUETIAPINE your doctor needs to know:

- Any other medical condition that you may have or previous history including heart diseases, seizures;
- Whether you are planning to get pregnant, are currently

pregnant or are nursing an infant;

- If you have neuroleptic malignant syndrome (a neurological disorder) with symptoms such as elevated body temperature, altered mental status and muscular rigidity.
- If you have severe neutropenia (an abnormally low count of neutrophils, a type of white blood cell)
- If you are a diabetic patient

- Taking other medicines

Tell your doctor if you are taking any other prescription or over-the-counter medication that you are currently taking, of particular seizure relief medications, such as carbamazepine. Other medications would include azole antifungals, macrolide antibiotic, protease inhibitors;

How to use Apo-Quetiapine

- How much to use

Adults:

Schizophrenia:

Quetiapine should be administered twice daily, with or without food.

Quetiapine should generally be administered with an initial dose of 25 mg twice daily, with increases in increments of 25-50 mg twice or thrice daily on the 2nd and 3rd day, as tolerated, to a target dose range of 300-400 mg daily by the 4th day, given twice or thrice daily.

Maintenance Treatment:

It is recommended that responding patients continued on quetiapine, but at the lowest dose needed to maintain remission.

Acute Manic Episodes Associated with Bipolar I Disorder:

Quetiapine should be administered twice daily, with or without food.

As a monotherapy or as adjunct therapy to mood stabilizers (lithium or divalproex), the total

daily dose for the first 4 days of therapy is 100 mg (day 1), 200 mg (day 2), 300 mg (day 3) and 400 mg (day 4). Further dosage adjustment up to 800 mg/day by day 6 should be in increments of no greater than 200 mg/day.

Depressive Episodes Associated with Bipolar Disorder:

Quetiapine should be administered once daily at bedtime, with or without food. Quetiapine should be titrated as follows: 50 mg (day 1), 100 mg (day 2), 200 mg (day 3) and 300 mg (day 4). Quetiapine can be titrated to 400 mg on day 5 and up to 600 mg by day 8.

Elderly:

As with other antipsychotics, quetiapine should be used with caution in the elderly, especially during the initial dosing period. Elderly patients should be started on quetiapine 25 mg/day. The dose should be increased daily, in increments of 25-50 mg, to an effective dose.

Children and Adolescents:

Not recommended.

Follow your doctor's instruction on how much to take, as dosage might differ for each and every individual.

- When to use it

APO-QUETIAPINE should be taken according to the doctor's instructions or the label attached with this medication. Swallow the tablet(s) with water and without chewing.

- How long to use it

Never increase or decrease the amount of APO-QUETIAPINE you, or those in your care if you are a caregiver or guardian, are taking unless your doctor tells you to and do not stop taking this medication without consulting your doctor.

- If you forget to use it

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As soon as you remember, take the missed dose. Unless it is almost time for your next scheduled dose, skip the missed dose. Do not take extra medicine to make up the missed dose.

- If you use too much (overdose)

Symptoms of overdose include drowsiness and sedation, a faster heart rate, low blood pressure.

Contact your doctor or nearest hospital emergency department even though you may not feel sick.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Quetiapine. Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give Apo-Quetiapine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

The side effects of taking APO-QUETIAPINE are usually mild and transient. The common side effects include: abnormal dreams, nightmares, dizziness, blurred vision, dry mouth, fluttering of the heart, weight gain, and constipation.

However, if you feel any other forms of discomfort when you take the medication, let your doctor know as soon as possible.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website np.ra.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Apo-Quetiapine

- Storage

Remember to keep APO-QUETIAPINE and all medications safely away from children.

Do not use this medicine after the month and year written after EXP on the container.

Store APO-QUETIAPINE at temperature below 30°C.

- Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product Description

- What it looks like

The 25mg tablets are peach coloured, round, biconvex, film-coated tablet. Engraved "APO" on one side, "QUE" over "25" on the other side.

The 100mg tablets are yellow coloured, round, biconvex, film coated tablet. Engraved 'APO' on one side, 'QUE' over '100' on the other side.

The 200mg tablets are white, round, biconvex, film coated tablet. Engraved 'APO' on one side. 'QUE' over '200' on the other side.

- Ingredients

The 25 mg tablets contain the active ingredient: Quetiapine Fumarate and the following non-active ingredients: Croscarmellose Sodium, Colloidal Silicon Dioxide, Fumaric Acid, Ethylcellulose N7FP, Magnesium Sterate, Hydroxypropyl Methylcellulose 2910, Hyrdoxypropyl Cellulose NF, Polyethylene Glycol 8000, Titanium Dioxide, Yellow Ferric Oxide NF, Red Ferric Oxide NF, Purified Water.

The 100 mg and 200mg tablets both contain the active ingredient: Quetiapine Fumarate and the following inactive ingredients: Croscarmellose Sodium, Colloidal Silicon Dioxide, Fumaric Acid, Ethylcellulose N7FP, Magnesium Sterate, Hydroxypropyl Methylcellulose 2910, Hyrdoxypropyl Cellulose NF, Polyethylene Glycol 8000, Titanium Dioxide, Yellow Ferric Oxide NF, Purified Water.

- MAL numbers:

APO-QUETIAPINE 25MG TABLETS
MAL10070575A
APO-QUETIAPINE 100MG TABLETS
MAL10070576A
APO-QUETIAPINE 200MG TABLETS
MAL10080063A

Manufacturer

Apotex Inc
150 Signet Drive,
Toronto, Ontario,
Canada, M9L 1T9

Product Registration Holder

Pharmaforte (M) Sdn Bhd
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Sunway Damansara
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1 Feb 2019

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