

APO-OLANZAPINE TABLETS

Olanzapine (5mg, 10mg)

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What Apo-Olanzapine is used for

Apo-Olanzapine (olanzapine) is indicated for the treatment and maintenance of schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.

Apo-Olanzapine is also indicated for the treatment of moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

How Apo-Olanzapine works

Apo-Olanzapine is in a class of medications called antipsychotics. It works by changing the activity of certain natural substances in the brain.

Before you use Apo-Olanzapine

- *When you must not use it*

Do not use this product if you are allergic to Olanzapine or any other ingredients in this medication. (Refer to **Product Description**)

Certain medical conditions do not allow the use of Apo-Olanzapine, such as narrow-angle glaucoma, Parkinson's disease, dementia-related psychosis and/or behavioural disturbances. Discuss with your

healthcare provider before you start to take this medication.

Pregnancy and lactation

Do not take Apo-Olanzapine if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Olanzapine if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

Before you start to use this medication, your doctor need to know if you have any other medication condition, which includes:

- Any medical condition mentioned in *When you must not use it* above.
- Any known liver, heart problems
- All other medical condition.

This medication may also affect your body temperature. Let your doctor know about your workplace environment so that they can determine whether or not this medication will affect your work.

Unless prescribed by the doctor, this medication is not suitable for the elderly and children.

- *Taking other medicines*

Some medication might cause complication when taken together with Apo-Olanzapine. These medications include:

- Activated charcoal
- Anti-parkinsonian medical products
- Medications for heart treatment

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Apo-Olanzapine

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Schizophrenia:

The recommended starting dose for olanzapine is 10 mg/day.

Bipolar Disorder:

The recommended starting dose is 10mg/day. For patients who have been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose.

Olanzapine can be given without regards for meals as absorption is not affected by food.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking Apo-Olanzapine for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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- *If you use too much (overdose)*

Common symptoms of overdose include tachycardia, agitation/aggressiveness, and dysarthria (speech difficulties).

Although there are no specific antidotes for this overdose, you should not try to vomit this medication. Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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-Olanzapine.

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-Olanzapine to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

This medication's metabolism will be affected by alcohol and smoking. Let your doctor/pharmacist know if you are going to smoke and/or consume

any alcohol during the treatment.

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

Like all medicines, Apo-Olanzapine can cause side effects, although not everybody gets them.

Below are some of the side effects that might occur:

- dizziness
- constipation
- fatigue
- weight gain
- akathisia (restlessness)
- orthostatic hypotension
- somnolence (sleepiness)
- dry mouth
- asthenia (physical weakness, lack of energy)
- dyspepsia (indigestion)
- increased appetite
- tremor

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Apo-Olanzapine

- *Storage*

Keep out of the reach and sight of children.

HDPE bottle: Store at below 25°C.

Protect from light and moisture.

Blister in box: Store below 30°C. Protect from light and moisture.

- *Disposal*

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.

Product Description

- *What it looks like*

5 mg tablets: Each white, round biconvex film-coated tablet, engraved "APO" on one side and "OLA" over "5" on the other side.

10 mg tablets: Each white, round biconvex film-coated tablet, engraved "APO" on one side and "OLA" over "10" on the other side.

- *Ingredients*

- Active ingredient
Olanzapine

- Inactive ingredients
Olanzapine Mix: Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Cornstarch

Olanzapine Film coating:
Hydroxypropyl Methyl Cellulose, Polyethylene Glycol, Titanium Dioxide, Purified Water.

- *MAL numbers:*

Apo-Olanzapine 5mg Tablets:
MAL19051005AZ
Apo-Olanzapine 10mg Tablets:
MAL19051006AZ

Manufacturer

Apotex Inc.
150 Signet Drive,

APO-OLANZAPINE TABLETS

Olanzapine (5mg, 10mg)

Toronto, Ontario,
Canada, M9L 1T9

Product Registration Holder

Pharmaforte (M) Sdn Bhd 2, Jalan
PJU 3/49, Sunway Damansara,
47810 Petaling Jaya, Selangor Darul
Ehsan

Date of revision

03/11/2020

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