

# OLENZA TABLET

Olanzapine (5mg, 10mg)

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## What OLENZA Tablet is used for

OLENZA Tablet is used to treat the following conditions:

- Schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.
- Short-term treatment of acute manic episode associated with Bipolar Disorder.

OLENZA has been shown to prevent recurrence of manic, depressive or mixed episodes in Bipolar Disorder.

## How OLENZA Tablet works

OLENZA TABLET contains the active ingredient Olanzapine. OLENZA TABLET belongs to a group of medicines called atypical antipsychotics.

It helps to correct chemical imbalances in the brain which may cause mental illness

## Before you use OLENZA Tablet

- When you must not use it
  - If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine.
  - OLENZA Tablet contains lactose. Do not take this medicine if you have intolerance to some kind of sugar called lactose
  - If you have been previously diagnosed with eye problems such

as certain kinds of glaucoma (increased pressure in the eye).

## - Before you start to use it

Tell your doctor if you:

- have had an allergic reaction to any medicine which you have taken previously to treat your current condition
- have or are at a risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking Olenza tablet and regularly during treatment
- Have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, or take oral contraceptives ("The Pill").
- are a smoker
- have ever had blackouts or seizures
- drink alcoholic beverages or use drugs
- have a history of liver problems, hepatitis, or yellowing of the eyes and skin (jaundice)
- have prostate problems
- have intestinal congestion (paralytic ileus)
- have Parkinson's disease
- blood disorder

## Pregnancy and breast feeding

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take OLENZA TABLET until you and your doctor have discussed the risks and benefits involved.

The following symptoms may occur in newborn babies, of mothers that have used Olenza tablet 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.

## - Taking other medicines

Tell all doctors, dentists and pharmacists who are treating you that you are taking OLENZA Tablet. Tell your doctor or pharmacist that you are taking OLENZA Tablet before you start taking any new medicines. A combination of OLENZA Tablet with the following medicines might make you feel drowsy:

- medicines taken for anxiety or to help you sleep
- medicines taken for depression.

You should tell your doctor if you are taking fluvoxamine (antidepressant), ketoconazole (antifungal), or ciprofloxacin (antibiotic), as these medicines may lead to higher concentrations of olanzapine in your blood.

You should also tell your doctor if you are taking carbamazepine as it may lead to lower concentrations of OLENZA Tablet in your blood, making OLENZA Tablet less effective.

Only take other medicines while you are on OLENZA Tablet if your doctor tells you that you can.

You can refer to your doctor or pharmacist for a more detail and complete list of medicines that may interact with Olanzapine

## How to use OLENZA Tablet

### - How much to use

The daily dose of OLENZA Tablet is between 5 and 20 mg

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

*Manic episode:* The starting dose is 15 mg as a single daily dose in monotherapy 10 mg daily in combination therapy.

*Preventing recurrence in bipolar disorder:* The recommended starting dose is 10mg/day.

*Elderly patients:* A lower starting dose (5mg/day) may be indicated for those 65 years old and above.

*Patients with renal and/or hepatic impairment:* A lower starting dose (5mg) may be given

Olanzapine is not recommended for use in children and adolescents below 18

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years of age due to a lack of data on safety and efficacy.

Your doctor may increase or decrease your dose in order to find the appropriate dose for your condition.

- When to use

Try to take your tablets at the same time each day. It does not matter whether you take them with or without food.

- How long to use it

Your doctor will tell you how many OLENZA Tablet tablets to take and how long you should continue to take them. Consult your doctor if your symptoms return but do not stop taking OLENZA Tablet unless your doctor tells you to.

The doctor will gradually taper off the dose if he thinks that you should stop taking OLENZA Tablet.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

- If you use too much (overdosage)

If you suspect an overdosage, contact your nearest hospital casualty department or tell your doctor immediately.

Symptoms of an overdose may include: fast heartbeat, agitation, slurred speech, and reduced consciousness from sedation to coma

**While you are using it**

- Things you must do

If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or “mini” stroke.

As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

Tell your doctor immediately if you become pregnant while taking OLENZA TABLET.

- Things you must not do

Do not drink any alcohol if you have been given OLENZA Tablet as together with alcohol it may make you feel drowsy.

- Things to be careful of

**Driving and using machines**  
Be careful driving or operating machinery until you know how OLENZA TABLET affects you. As with other antipsychotic medicines, OLENZA TABLET may cause tiredness, drowsiness, dizziness, light-headedness, fainting or seizures (fits) in some people, especially at the start of treatment.

Make sure you know how you react to OLENZA TABLET before you drive a car, operate machinery or do anything else that could be dangerous.

**Side effects**

Like all medicines, Olenza tablet can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Tell your doctor immediately or go to accident and emergency department at your nearest hospital if you notice any of the following:

- Sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips or tongue; wheezing or troubled breathing
- symptoms of neuroleptic malignant syndrome, with a sudden increase in body temperature, excessive sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma
- Seizures (fits)
- yellowing of the skin and/or eyes, sometimes accompanied by feeling sick and loss of appetite Your doctor will need to check your liver.
- Increases in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination)

- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)

- Trouble breathing during sleep (sleep apnoea)

- Difficulty or inability to pass urine (urinary retention)

Very common side effects include:

- Weight gain.
- Sleepiness.
- Increases in levels of prolactin (a type of hormone) in the blood.
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Very rare: Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of OLENZA Tablet**

- Storage

Store below 30°C

- 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.

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## Product Description

- What it looks like

OLENZA TABLET 5MG TABLET: A white to off white round shaped film coated tablet with score on one side with a diameter of 8mm

OLENZA TABLET 10MG TABLET: A white to off white round shaped film coated tablet with score on one side with a diameter of 10.1mm

- Ingredients

- Active ingredient

Olanzapine

- Inactive ingredients

Colloidal silicon dioxide, Hydroxypropyl cellulose, Polyethylene glycol 400, Polyethylene glycol 6000, Lactose monohydrate, Polysorbate 80, Hydroxypropylmethyl cellulose, Titanium dioxide, Microcrystalline cellulose, Magnesium stearate, Talc, Crospovidone, Isopropyl alcohol, Polyvinylpyrrolidone, and Ethylcellulose.

- MAL number:

OLENZA TABLET 5MG  
TABLET: MAL10100149AZ  
OLENZA TABLET 10MG  
TABLET: MAL10100148AZ

## Product Registration Holder and Manufacturer:

Noripharma Sdn. Bhd.  
Lot 5030, Jalan Teratai,  
5 ½ Mile off Jalan Meru  
41050 Klang, Selangor

## Date of Revision

February 2022

## Serial number:

NPRA(R2/1)211203/802