

OLANZ TABLETS 5MG

OLANZ TABLETS 10MG

Olanzapine (5mg, 10mg)

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What OLANZ Tablets is used for

OLANZ Tablets is used for the acute and maintenance treatment of schizophrenia (a mental disorder that affects how a person thinks, feels and behaves).

How OLANZ Tablets works

Olanzapine is the active ingredient of OLANZ Tablets. OLANZ Tablets is an antipsychotics. It works by helping to restore the chemical imbalances in the brain which may cause mental disorder.

Before you use OLANZ Tablets

-When you must not use it

- If you are allergic (hypersensitive) to Olanzapine or any of the other ingredients of this medicine.
- If you have been previously diagnosed with narrow-angle glaucoma (increased pressure in the eye).

-Before you start to use it

You must tell your doctor if you have the following conditions:

- Hyperglycemia (an excess of blood sugar level) and diabetes.
- Dementia or behavioral disturbances
- Parkinson's disease
- Neuroleptic Malignant Syndrome (potentially life-threatening idiosyncratic reaction to antipsychotic drugs)
- Dyslipidemia (abnormal amount of lipids in the blood)
- Prostatic hyperthrophy and paralytic ileus (obstruction of intestine due to paralysis of the intestinal muscle)

- Liver impairment or taking medicines that may produce injury to the liver.
- Low count of white blood cells and/or neutrophil (most common type of white blood cell)
- Heart problems such as congenital long QT syndrome (a heart rhythm condition that cause irregular heartbeats), congestive heart failure, heart hypertrophy (thickening of heart muscle)
- Thromboembolism (obstruction of blood vessel by blood clot)
- Seizures
- Tardive dyskinesia (a neurological disorder characterised by uncontrolled muscle movements of the face and jaw).

OLANZ Tablets should be used with caution if you are:

- Taking other centrally acting medicines
- Alcohol

It is recommended that blood pressure is measured periodically if you are over 65 years to avoid postural hypotension.

Children and adolescents:

This medicine is not recommended for use in children and adolescents below 18 years.

Pregnancy and breastfeeding:

You should tell your doctor if you are pregnant, think that you may be pregnant, or planning to become pregnant. Do not take OLANZ Tablets until you and your doctor have discussed the risks and benefits involved.

The following extrapyramidal and/or withdrawal symptoms may occur in newborn babies, of mothers that have used OLANZ in the last trimester (last three months of their pregnancy): agitation, muscle stiffness and/or weakness, shaking, sleepiness, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not use this medicine if you are breast-feeding. This is because small amount may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

-Taking other medicines

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

In particular, tell your doctor if you are taking:

- Dopamin agonist (medicines for Parkinson's disease)
- Carbamazepine (an anti-epileptic and mood stabilizer)
- Fluvoxamine (an antidepressant)
- Ciprofloxacin (an antibiotic)
- Ketoconazole (an antifungal)
- Activated charcoal tablets

How to use OLANZ Tablets

-How much to use

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

Schizophrenia:

Recommended starting dose for olanzapine is 10mg/day

Manic episode:

Starting dose is 15mg as a single dose in monotherapy or 10mg daily in combination therapy.

Preventing recurrence in bipolar disorder:

The recommended starting dose is 10mg/day.

During treatment for schizophrenia, manic episode and recurrence prevention in bipolar disorder, daily dosage may subsequently be adjusted by your doctor within the range 5-20mg /day.

Elderly patients:

The doctor may start at a lower starting dose (5mg/day) especially those 65 years old and above if required.

Gender:

The starting dose and dose range need not be routinely altered for female patients relative to male patients.

Smokers:

The starting dose and dose range need not be routinely altered for non-smoking patients relative to smoking patients.

Patients with renal and/or hepatic impairment:

A lower starting dose (5mg) should be considered for such patients. In cases of moderate hepatic insufficiency (cirrhosis, Child-Pugh Class A or B), the starting dose should be 5mg and only increased with caution.

-When to use it

Use as directed by your doctor or pharmacist. Take this medicine only by mouth with water.

-How long to use it

Continue taking this medicine for as long as your doctor recommends.

-If you forget to use it

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

-If you use too much (Overdose)

Symptoms: high heart rate, agitation/aggressiveness, problems with speech, unusual movements especially of the face or tongue and reduced level of consciousness.

Other symptoms: confusion, seizures (epilepsy), coma, neuroleptic malignant syndrome (combination of fever, altered mental status, and muscle stiffness), slowing of the breathing rate, aspiration, high or low blood pressure, abnormal rhythms of the heart, heart attack.

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 there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using OLANZ Tablets

-Things you must do

Contact your doctor if your symptoms worsen or they do not improve.

If you do become pregnant whilst taking OLANZ Tablets, tell your doctor.

-Things you must not do

Do not give OLANZ Tablets to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed OLANZ Tablets for you and your condition.

This medicine is not recommended for breastfeeding mothers.

-Things to be careful of

This tablet may cause drowsiness, dizziness or less alertness. Please avoid taking this tablet if you need to operate any machinery or drive any vehicles. Avoid from alcohol consumption.

Tell your doctor if you experience any discomforts after taking this medicine.

Side Effects

Like all medicines, OLANZ Tablets can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Somnolence
- Weight gain
- Eosinophilia (high count of one type of white blood cell)
- Elevated prolactin (a type of hormone), cholesterol, glucose and triglyceride
- Glucosuria (presence of glucose in urine)
- Increased appetite
- Dizziness
- Akathisia (a type of movement disorder)
- Symptoms of parkinson
- Dyskinesia (impairment of voluntary movement)
- Orthostatic hypotension (low blood pressure when standing)
- Temporary elevated level of liver enzymes
- Rash

- Asthenia (abnormal physical weakness)
- Fatigue
- Oedema (swelling of soft tissues as a result of excess fluid accumulation).

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 body temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia).

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. Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of OLANZ Tablets

-Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

OLANZ Tablets should be stored in the original package and in a dry place.

Do not store above 30°C.

Keep out of the reach and sight of children.

-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

OLANZ Tablets 5mg

A yellow, scored, convex of diameter 8.5mm round tablet with "MPI" marking.

OLANZ Tablets 10mg

A yellow, scored, convex of diameter
11mm round tablet.

- Ingredients

- Active Ingredient:

OLANZ Tablets 5mg

Each tablet contains Olanzapine 5mg.

OLANZ Tablets 10mg

Each tablet contains Olanzapine 10mg.

- Inactive ingredients:

Anhydrous Lactose, Copovidone
(Plasdone S-630), Crospovidone,
Colloidal Silicon Dioxide, and
Magnesium Stearate.

-MAL number:

**Manufacturer and Product
Registration Holder**

Malaysian Pharmaceutical Industries Sdn.
Bhd.

Plot 14, Lebuhraya Kampung Jawa,
11900 Bayan Lepas, Penang, Malaysia.

Date of Revision

11/07/2017