

# OLEANZ TABLET

Olanzapine (5 mg, 10 mg)

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## What *Oleanz* is used for

*Oleanz* is indicated for the acute and maintenance treatment of schizophrenia (a mental illness with disturbances in thinking, feelings and behaviour).

## How *Oleanz* works

*Oleanz* contains the active ingredient Olanzapine. *Oleanz* belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain which may cause mental illness.

## Before you use *Oleanz*

- When you must not use it

Do not take *Oleanz* if you

- have an allergy to Olanzapine, the active ingredient, or to any of the other ingredients of *Oleanz* listed at the end of this leaflet (see section **Product description**).
- known risk for narrow angle glaucoma (a condition in which there is usually a build-up of fluid in the eye).

- Before you start to use it

Tell your doctor if you have or have had any medical conditions or illnesses, especially the following:

- Prostatic hypertrophy (age-associated prostate gland enlargement that can cause urination difficulty).
- Paralytic ileus (obstruction of the intestine due to paralysis of the intestinal muscles)
- Liver impairment or taking medicines that may produce injury to the liver.
- Low count of white blood cells and/or neutrophils (most common type of white blood cells)

- Hyperglycaemia (an excess of glucose in the bloodstream, often associated with diabetes)
- Diabetes mellitus
- Neuroleptic malignant syndrome (NMS) (potentially life-threatening condition associated with some medicines) (see section **Side effects**)
- Tardive dyskinesia (a neurological disorder characterised by uncontrolled muscle movements of the face and jaw)
- Seizures (fits)

*Oleanz* should be used with caution if you are:

- taking alcohol
- smoking

## Pregnancy and breastfeeding

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take *Oleanz* 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 *Oleanz* 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 amounts 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

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

Talk to your doctor or pharmacist before you take *Oleanz* with:

- Carbamazepine (used to control fits)

- Fluvoxamine (used to treat depression)
- Activated charcoal
- Dopamine agonist (used to treat Parkinson's disease)

Other medicines not listed above may also interact with *Oleanz*. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking *Oleanz*.

## How to use *Oleanz*

- 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 *Oleanz* is 10mg/day.

The dose may be subsequently adjusted within the range 5 - 20 mg/day based on your individual response.

## **Children:**

*Oleanz* is not for individuals who are under 18 years.

## **Elderly :**

A lower starting dose (5 mg/day) is not routinely indicated but should be considered for those 65 and over when clinical factors warrant.

## **Individual with liver and/or kidney impairment:**

A lower starting dose (5 mg) may be considered for such individuals.

- When to use it

Use as directed by your doctor or pharmacist.

You can take your *Oleanz* tablets with or without food.

- How long to use it

Continue taking *Oleanz* for as long as your doctor recommends.

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– 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.

If you use too much (overdose)

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.

Taking too many tablets may cause:

- Tachycardia (an abnormally rapid heart rate)
- Agitation / Aggressiveness
- Dysarthria (difficulty speaking caused by problems controlling the muscles used in speech)
- Various extrapyramidal symptoms (e.g. parkinsonism or motor restlessness)
- Reduced level of consciousness
- Acute confusional state
- Seizure (fits)
- Coma
- Neuroleptic malignant syndrome (see section **Side effects**)
- Respiratory depression
- Aspiration (a condition when food, liquids, saliva, or vomit is breathed into the airways)
- High blood pressure
- Low blood pressure
- Cardiac arrhythmias (irregular heartbeat)
- Cardiac arrest (a condition when the heart suddenly stops beating effectively)

**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 that are treating you that you are taking *Oleanz*.

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. Your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give *Oleanz* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

The blood pressure need to be measured periodically in people over 65 years as postural low blood pressure was infrequently observed in the elderly.

Driving and using machines

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

**Side effects**

Like all medicines, *Oleanz* 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.

The frequent side effect include:

- Weight gain
- Somnolence (sleepiness)

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- symptoms of neuroleptic malignant syndrome (e.g. a sudden increase in body temperature, muscle stiffness, fast and/or irregular heartbeat, sweating, and altered mental status)
- cold, fever, flu-like symptoms, sore throat or any other signs of infection. You will have to have an urgent blood test to check if your

symptoms are related to your medicine.

- symptoms of tardive dyskinesia (uncontrolled involuntary purposeful movements of the tongue, face, mouth or jaw) and/or tardive extrapyramidal syndromes (e.g. abnormal, uncontrolled muscle movements)

Very rare: Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with as 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).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

**Storage and Disposal of *Oleanz***

– Storage

Keep out of the reach and sight of children.

Store below 25°C. Protected from light

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

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– 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.

**Serial Number**

BPFK(R4/1)041115/00397

**Product Description**

– What it looks like

**OLEANZ 5 TABLET**

Yellow colored, oval shaped, uncoated tablets debossed with “5” on one side & scored on the other side.

**OLEANZ 10 TABLET**

Yellow colored, oval shaped, uncoated tablets debossed with “10” on one side & scored on the other side.

– Ingredients

- Active ingredient  
Olanzapine
- Inactive ingredients  
Microcrystalline Cellulose  
Magnesium stearate  
Crossprovidone  
Low substituted Hydroxy propyl-cellulose  
Anhydrous Lactose  
Colloidal Silicon Dioxide

MAL numbers:

**OLEANZ 5 TABLET:**

MAL10100139AZ

**OLEANZ 10 TABLET:**

MAL10100143AZ

**Manufacturer**

Sun Pharmaceutical Industries Ltd  
Halol-Baroda Highway,  
Halol-389 350, Gujarat  
India.

**Product Registration Holder**

Pahang Pharmacy Sdn. Bhd.  
Lot 5979, Jalan Teratai,  
5 ½ Mile Off Jalan Meru,  
41050 Klang, Selangor  
Malaysia

**Date of revision**

13/04/2017