

OLANGEM OD Tablets

Consumer Medication Information Leaflet (RiMUP)

Olanzapine (5 mg, 10 mg)

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What is OLANGEM OD used for

Olanzapine belongs to a group of medicines called antipsychotics and 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

-Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria. Olanzapine has been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

How OLANGEM OD works

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

Before you use OLANGEM OD

-When you must not use it

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine. An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of

breath or any other unusual symptoms. If this has happened to you, tell your doctor.

- 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

Talk to your doctor or pharmacist before you take Olangem OD.

- The use of Olangem OD in elderly patients with dementia is not recommended as it may have serious side effects.
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olangem OD tell your doctor.
- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.
- Weight gain has been seen in patients taking Olangem OD. You and your doctor should check your weight regularly.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking Olangem OD. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olangem OD and regularly during treatment.
- Tell the doctor if you or someone else in your family has a history of blood clots, as medicines like these have been associated with the formation of blood clots.
- Talk to your doctor or pharmacist if you have or are at 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 OLANGEM OD and regularly during treatment.

If you suffer from any of the following illnesses tell your doctor as soon as possible:

- Stroke or “mini” stroke (temporary symptoms of stroke)
- Parkinson’s disease
- Prostate problems
- A blocked intestine (Paralytic ileus).
- Liver or kidney disease
- Blood disorders
- Heart disease
- Diabetes
- Seizures

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.

Children and adolescents

Olangem OD is not for patients who are under 18 years.

-Taking other medications

Only take other medicines while you are on Olangem OD if your doctor tells you that you can. You might feel drowsy if Olangem OD is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

You should tell your doctor if you are taking fluvoxamine (an antidepressant), or ciprofloxacin (an antibiotic), as it may be necessary to change your Olangem OD dose.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking medicines for Parkinson’s disease.

How to use OLANGEM OD

-How much to use

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

Your doctor will tell you how many Olangem OD to take and how long you should continue to take them. The

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daily dose of Olangem OD is between 5 mg and 20 mg. Consult your doctor

if your symptoms return but do not stop taking Olangem OD unless your doctor tells you to.

-When to use it

You should take your Olangem OD once a day following the advice of your doctor.

Olangem OD are for oral 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 long you should continue to take Olangem OD.

-If you forget to use it

Take your tablets as soon as you remember. Do not take two doses in one day.

-If you use too much (overdose)

If you have accidentally taken more than your prescribed dose, contact your doctor or hospital straight away. Show the doctor your pack of tablets.

While you are using it

-Things you must do

If you feel unwell or if you have concerns about a side effect, you will need to seek advice. If you feel very ill, get medical help straight away. If you have any unused medicine, return it to your pharmacist who will dispose it of safely. These measures will help to protect the environment.

-Things you must not do

You must not take the medicine after the expiry date shown on the packaging.

-Things to be careful of

Driving and using machines

- Some people feel dizzy or tired when taking this medicine. If this happens to you, do not drive or use any tools or machines.

- You must wait to see how your medicine affects you before trying these activities.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have:

- Unusual movement mainly of the face or tongue.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- A combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness.
- Weight gain
- Sleepiness
- Increases in levels of prolactin in the blood.
- Changes in the levels of some blood cells and circulating fats.
- Increases in the level of sugars in the blood and urine.
- Feeling more hungry.
- Dizziness
- Restlessness
- Increased cholesterol level
- Increased triglyceride level
- Rashes
- Tremor muscle stiffness or spasm (including eye movements) problems with speech
- Constipation
- Dry mouth
- Sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males
- Pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and trouble walking found in elderly patient.
- 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)
- If you have any other symptoms which you have not experienced before.

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 Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nppra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of OLANGEM OD

-Storage

Keep this medicine out of the reach and sight of children. Do not use Olangem OD after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

Do not store above 30°C.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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Product Description

-What it looks like

OLANGEM OD 5: Yellow colored, circular, flat faced beveled edge tablets, debossed with “C” on one side and “51” on the other side.

OLANGEM OD 10: Yellow colored, circular, flat faced beveled edge tablets, debossed with “C” on one side and “52” on the other side.

Available in blister packs of 28's.

-Ingredients

· Active ingredient(s)

The active substance is Olanzapine.

OLANGEM OD 5:

Each orodispersible tablet contains Olanzapine 5 mg.

OLANGEM OD 10:

Each orodispersible tablet contains Olanzapine 10 mg.

· Inactive ingredient(s)

Other ingredients are Mannitol (Pearlitol SD 200), Mannitol (Mannitol 35), Polacrillin potassium, Crospovidone (Type A), Silica Colloidal Anhydrous, Aspartame, Cellulose microcrystalline (PH-112), Sodium Stearyl Fumarate, Art Pineapple.

-MAL number

OLANGEM OD 5

MAL17107085AZ

OLANGEM OD 10

MAL17107086AZ

Manufacturer

Aurobindo Pharma Limited Unit VII, SEZ, TSIIC, Plot. No.SI, Survey No's: 411/P, 425/P, 434/P, 435/P & 458/P' Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboobnagar District, Telangana State, India.

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd, No. 74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300, Kuala Lumpur, Malaysia.

Date of revision

13/05/2019

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