

OLANGEM

Olanzapine Tablets 5 & 10 mg

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What is OLANGEM used for

OLANGEM is used to treat the following conditions:

- Schizophrenia, a mental 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

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

How OLANGEM works

OLANGEM is an antipsychotic, antimanic and mood stabilising agent. OLANGEM contains the active ingredient olanzapine. OLANGEM 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 OLANGEM

-When you must not use it

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (see section Product description). An allergic reaction may be recognised as

a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.

- If you have Parkinson's disease.
- If you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).
- The use of OLANGEM in elderly with dementia (symptoms that may include memory loss and difficulties with thinking, problem-solving or language) is not recommended as it may have serious side effects.

-Before you start to use it

Talk to your doctor or pharmacist before you take OLANGEM.

- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in individuals taking OLANGEM. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking OLANGEM 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.
- If you 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 OLANGEM 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)
- Prostate enlargement
- A blocked intestine (Paralytic ileus)
- Liver or kidney disease
- Blood disorders
- Heart disease
- Diabetes

- Seizures

Pregnancy and Lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not be given this medicine when breast-feeding, as small amounts of OLANGEM can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used OLANGEM 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 medications

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

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- medicines for Parkinson's disease
- carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant), charcoal or ciprofloxacin (an antibiotic) - it may be necessary to change your OLANGEM dose.

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

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

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How to use OLANGEM

-How much to use

Your doctor will tell you how many OLANGEM tablets to take and how long you should continue to take them. The daily dose of OLANGEM is between 5 mg and 20 mg. Consult your doctor if your symptoms return but do not stop taking OLANGEM unless your doctor tells you to.

Children and adolescents: OLANGEM is not for children and adolescents under 18 years.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

-When to use it

You should take your OLANGEM tablets normally once a day following the advice of your doctor or pharmacist.

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

OLANGEM tablets should be swallowed whole with a glass of water.

-How long to use it

Continue taking OLANGEM for as long as your doctor recommends.

-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)

Individuals who have taken more OLANGEM than they should have experienced the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness. Other symptoms may be: acute confusion, seizures (epilepsy), coma, and high fever, faster breathing, sweating, muscle stiffness, slowing of the

breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart.

Contact your doctor or hospital straight away if you experience any of the above symptoms. Show the doctor your pack of tablets.

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 OLANGEM.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking your tablets just because you feel better. It is important that you carry on taking OLANGEM for as long as your doctor tells you.

If you suddenly stop taking OLANGEM, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-Things to be careful of

There is a risk of feeling drowsy when you are given OLANGEM. If this happens do not drive or operate any tools or machines. Tell your doctor.

OLANGEM tablet contains lactose

If you have been told by your doctor that you have an intolerance to some sugar, contact your doctor before taking this medicinal product.

Side effects

Weight gain

Weight gain has been seen in individuals taking OLANGEM. You and your doctor should check your

weight regularly. Consider referral to a dietician or help with a diet plan if necessary.

Elderly

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

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

Tell your doctor immediately if you have:

- unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue;
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) 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. If you notice any of these symptoms seek medical advice immediately;
- A combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (rare side effects [may affect up to 1 in 1000 people]);
- Increase 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 (may affect more than 1 in 10 people) include weight gain; sleepiness; and increases in levels of prolactin 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.

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Common side effects (may affect up to 1 in 10 people) include changes in the levels of some blood cells, circulating fats and early in treatment, temporary increases in liver enzymes; increases in the level of sugars in the blood and urine; increases in levels of uric acid and creatine phosphokinase in the blood; feeling more hungry; dizziness; restlessness; tremor; constipation; dry mouth; rash; loss of strength; extreme tiredness; water retention leading to swelling of the hands, ankles or feet; fever; joint pain; and sexual dysfunctions such as decreased libido (sexual desire) in males and females or erectile dysfunction (inability to get and maintain an erection) in males.

Uncommon side effects (may affect up to 1 in 100 people) include hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (build up of acid in the blood) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms (including eye movements); restless legs syndrome; problems with speech; stuttering; slow heart rate; sensitivity to sunlight; bleeding from the nose; abdominal distension; drooling; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence in menstrual periods and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects (may affect up to 1 in 1000 people) include lowering of normal body temperature; abnormal rhythms of the heart; sudden death; inflammation of the pancreas causing severe stomach pain, fever and sickness; liver disease appearing as yellowing of the skin and white parts of the eyes; muscle disease presenting as unexplained aches and pains; and prolonged and/or painful erection.

Very rare side effects include 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 on blood tests and an increase in a type of white blood cells (eosinophilia).

While taking olanzapine, elderly with dementia may suffer from stroke, pneumonia (infection that leads to inflammation of the lungs), urinary incontinence, falls, extreme tiredness, visual hallucinations (seeing things that are not real), a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of individuals.

In people with Parkinson's disease OLANGEM may worsen the symptoms.

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

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 OLANGEM

-Storage

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date, which is stated on the carton.

Store below 30°C. Store in the original package in order to 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

OLANGEM 5 mg Tablets- Yellow coloured, circular, biconvex uncoated tablets, debossed with 'OA' on one side and '5' on the other side

OLANGEM 10mg Tablets- Yellow coloured, circular, biconvex uncoated tablets, debossed with 'OA' on one side and '10' on the other side.

-Ingredients

- Active ingredient(s)
- Olanzapine

- Inactive ingredient(s)
- Lactose monohydrate, Hydroxypropyl cellulose, Crospovidone, Magnesium stearate

-MAL number

MALXXXXXXXXX

Manufacturer

Aurobindo Pharma Limited - Unit VII
Special Economic Zone, TSIIC, Plot No. S1, Sy. No's 411/P; 425/P; 434/P; 435/P and 458/P, Green Industrial Park, Polepally Village, Jadcherla Mandal, Mahabubnagar, 509302, India.

Product Registration Holder

Healol Pharmaceuticals Sdn Bhd,
74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300, Kuala Lumpur, Malaysia.

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