

Olmac Tablet

Olanzapine Film-Coated Tablets USP (5mg & 10mg)

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1. WHAT OLMAC ARE USED FOR:

Olmac is indicated for the treatment and maintenance of schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.

Olmac is also indicated for the treatment of moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

2. HOW OLMAC WORKS:

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

3. BEFORE YOU USE OLMAC

When you must not use it

If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine.

Certain medical conditions do not allow the use of Olmac, such as narrow-angle glaucoma, Parkinson's disease, dementia-related psychosis and/or behavioural disturbances.

Discuss with your healthcare provider before you start to take this medication.

Pregnancy and lactation

Do not take Olmac if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Olmac if you are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Your doctor need to know if you have any other medication condition, which includes:

- Any medical condition mentioned in the sub-header

When you must not use it.

- Any known liver, heart problems
- All other medical condition.

This medication may also affect your body temperature. Let your doctor know about your workplace environment so that they can determine whether or not this medication will affect your work. Unless prescribed by the doctor, this medication is not suitable for the elderly and children.

- Taking other medicines

Some medication might cause complication when taken together with Olmac. These medications include:

- Activated charcoal
- Anti-parkinsonian medical products
- Medications for heart treatment

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

4. HOW TO USE OLMAC:

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 olanzapine is 10 mg/day.

Bipolar Disorder:

The recommended starting dose is 10mg/day. For patients who have

been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose.

Olanzapine can be given without regards for meals as absorption is not affected by food.

When to use it:

Use as directed by your doctor or pharmacist.

How long to use it:

Continue taking Olmac for as long as your doctor recommends.

If you forget to take

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):

Common symptoms of overdose include tachycardia, agitation/aggressiveness, and dysarthria (speech difficulties).

Although there are no specific antidotes for this overdose, you should not try to vomit this medication. 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.

5. WHILE YOU ARE USING OLMAC:

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

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- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Olmac to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of:

This medication's metabolism will be affected by alcohol and smoking. Let your doctor/ pharmacist know if you are going to smoke and/or consume any alcohol during the treatment.

Driving and using machines:

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

6. SIDE EFFECTS

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

Below are some of the side effects that might occur:

- dizziness
- constipation
- fatigue
- weight gain
- akathisia (restlessness)
- orthostatic hypotension
- somnolence (sleepiness)
- dry mouth
- asthenia (physical weakness, lack of energy)
- dyspepsia (indigestion)
- increased appetite
- tremor

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. STORAGE AND DISPOSAL OF OLMAC:

Storage

Store below 30°C.
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.

8. PRODUCT DESCRIPTION

What it looks like and contents of the pack

Olmac 5: White to off white coloured, round shaped, biconvex, film coated tablets having 'CL 40' debossed on one side and plain on other side.

Olmac 10: White to off white coloured, round shaped, biconvex, film coated tablets having 'CL 42' debossed on one side and plain on other side.

Olmac are available in pack of:
Alu/Alu Blister pack of 10 tablets.
Available in pack size of 3 x 10's

What Olmac contains

Active ingredient

The active substance is Olanzapine.

Inactive ingredients

The other ingredients are:
Microcrystalline cellulose, low-substituted hydroxypropyl cellulose, crospovidone, magnesium stearate, Opadry White AMB OY-B-28920, and purified water

-MAL No:

Olmac 5: MAL23096021AZ

Olmac 10: MAL23096022AZ

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer:

MACLEODS

PHARMACEUTICALS LTD.

Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh-174101, India.

Office address: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059.

Product Registration Holder:

Macleods Pharmaceutical Sdn. Bhd.

A2-27-1 Soho Suites KLCC, Jalan Perak, 50450 Kuala Lumpur, Malaysia.

10. Date of revision

26/08/2024

11. Serial Number

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