

# Hovid Olanzapine Orodispersible Tablets

Olanzapine (5mg, 10mg)

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## What Hovid Olanzapine Orodispersible Tablets is used for

Olanzapine 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.
- Hovid Olanzapine Orodispersible Tablets has been shown to prevent recurrence of manic, depressive or mixed episodes in Bipolar Disorder.

## How Hovid Olanzapine Orodispersible Tablets works

Olanzapine 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 Hovid Olanzapine Orodispersible Tablets

### - 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. 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).
- If you have Parkinson's disease

### - Before you start to use it

Talk to your doctor or pharmacist before you take olanzapine.

- 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 Hovid Olanzapine ODT tablets and regularly during treatment.
- The use of olanzapine 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 olanzapine 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 olanzapine. 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 olanzapine. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking olanzapine 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 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

Olanzapine is not for patients who are under 18 years.

### - Taking other medicines

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

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

Do not drink any alcohol if you have been given Hovid Olanzapine Orodispersible Tablets as together with alcohol it may make you feel drowsy.

In particular, tell your doctor if you are taking:

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

## How to use Hovid Olanzapine Orodispersible Tablets

### - How much to use

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

Your doctor will tell you how many olanzapine tablets to take and how long

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you should continue to take them. The daily dose of olanzapine is between 5 mg and 20 mg. Consult your doctor if your symptoms return but do not stop taking Hovid Olanzapine Orodispersible Tablets unless your doctor tells you to.

**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 5-20 mg/day.

**Children:** Olanzapine is not recommended for use in children and adolescents below 18 years.

**Elderly patients:** The doctor may start at a lower starting dose (5mg/day) especially those 65 and above when clinical factors warrant.

**Patients with kidney and/or liver 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 5 mg and only increased with caution.

## Smokers

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

When more than one factor is present which might result in slower metabolism (female gender, geriatric age, non-smoking status), consideration should be given to decreasing the starting dose.

## - When to use it

You should take your Hovid Olanzapine Orodispersible Tablets once a day following the advice of your doctor. Try to take your tablets at the same time each day. It does not matter whether you take them with or without food. Hovid Olanzapine Orodispersible Tablets are for oral use. The tablet should be placed in the mouth where it will rapidly disperse in saliva, so it can be easily swallowed. Removal of the intact olanzapine tablet from the mouth is difficult. Since the olanzapine tablet is fragile, it should be taken immediately on opening the blister. Alternately, it may be dispersed in a full glass of water or other suitable beverage (orange juice, apple juice, milk or coffee) immediately before administration.

You should handle Hovid Olanzapine ODT tablets carefully.

- Hold the blister strip
- Carefully peel off the backing.
- Gently push the tablet out.
- Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

## - How long to use it

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

If you suddenly stop taking olanzapine, 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.

## - 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)

Patients who have taken more olanzapine 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, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, 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

## **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, 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 olanzapine can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used Hovid Olanzapine Orodispersible Tablets 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.

### - Things you must not do

## **Driving and using machines**

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

### - Things to be careful of

**Hovid Olanzapine ODT** contains aspartame, mannitol, low-substituted hydroxypropyl cellulose, silica and magnesium stearate.

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People who cannot take phenylalanine should note that Hovid Olanzapine ODT contains aspartame, which is a source of phenylalanine. It may be harmful for people with phenylketonuria.

People who cannot take mannitol should note that Hovid Olanzapine ODT contains mannitol.

Hovid Olanzapine ODT contains low-substituted hydroxypropyl cellulose which may cause an allergic reaction in some people. An allergic reaction may be recognized as a rash, itching or shortness of breath. This may occur immediately or sometime after you take Hovid Olanzapine ODT.

## Side effects

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

Talk to your doctor or pharmacist if you experience:

- 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)
- unusual movement (a common side effect) mainly of the face or tongue;
- Blood clots in the veins (an uncommon side effect) 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).

Tell your doctor if any of the below side effects starts bothering you;

- Very common side effects: 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.
- Common side effects: 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; unusual movements (dyskinesias); 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 in males and females or erectile dysfunction in males.
- Uncommon side effects: hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms ( including eye movements; problems with speech; stuttering; slow heart rate; sensitivity to sunlight; bleeding from the nose; abdominal distension; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease 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: lowering of normal body temperature; abnormal rhythms of the heart; sudden unexplained 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: 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 patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

- In patients with Parkinson's disease Hovid Olanzapine Orodispersible may worsen the symptoms
- Hovid Olanzapine Orodispersible Tablets contains aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.
- If you have any other symptoms which you have not experienced before.

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](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of Hovid Olanzapine Orodispersible Tablets

### - Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light and moisture.

Do not take your tablets after the expiry date (EXP) shown on the carton or

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blister foil. The expiry date refers to the last day of that month.

121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar), 30010 Ipoh, Malaysia.

## - Disposal

Remember to return any unused medicine to your pharmacist.

## **Date of revision**

10/11/2021

Medicines should not be disposed of via wastewater or household waste.

## **Serial Number**

NPRA (R2) 19/155

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

Hovid Olanzapine Orodispersible Tablets 5mg are yellow coloured, round, flat face bevelled edge tablets with characteristic flavour, debossed with "D5" on one side and "CO" on other side.

Hovid Olanzapine Orodispersible Tablets 10mg are yellow coloured, round, flat face bevelled edge tablets with characteristic flavour, debossed with "D10" on one side and "CO" on other side

Pack size: Blister packs of 3 x 10's

### - Ingredients

- Active ingredient:

Olanzapine

- Inactive ingredients:

Mannitol, Low-substituted Hydroxypropyl cellulose, Aspartame, Strawberry flavour, silica, colloidal anhydrous, magnesium stearate

### - MAL numbers

5mg: MAL20046109ACZ

10mg: MAL20046108ACZ

## **Manufacturer**

Jubilant Generics Ltd.,  
Village Sikandarpur Bhainswal,  
Roorkee-Dehradun Highway,  
Bhagwanpur, Roorkee, District-  
Haridwar, Uttarakhand – 247661, India.

## **Product Registration Holder**

Hovid Berhad.,