

ONZAPIN ORODISPERSIBLE TABLETS

Olanzapine orodispersible (5mg,10mg)

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What Onzapin is 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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 Onzapin 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 Onzapin

-When you must not take it

Do not take olanzapine:

-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).

-Before you start to take it

Talk to your doctor or pharmacist before you take olanzapine:

-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 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 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 Olanzapine tablets 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

-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.

Pregnancy and breast-feeding

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 olanzapine can pass into breast milk.

The following symptoms may occur in newborn babies of mothers that have used olanzapine 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.

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.

-Taking other medicines

Only take other medicines while you are on olanzapine 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. In particular, tell your doctor if you are taking:

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- 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.
- Activated charcoal, for general detoxification, digestion issues, gas, bloating

How to take Onzapin

-How much to take

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

-When to take it

You should take your Olanzapine 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.

-How long to take it

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

-If you forget to take it

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

-If you take 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)
- Reduced level of consciousness.

Other symptoms may be:

- Acute confusion,
- Seizures (epilepsy),
- A combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness,
- Slowing of the breathing rate, aspiration, coma,
- 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 Onzapin

-Things you must do

Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

You can also place the tablet in a full glass or cup of water and stir. Drink it straight away.

-Things you must not do

Olanzapine tablets break easily, so you should handle the tablet carefully. Do not handle the tablets with wet hands as the tablets may break up.

-Things to be careful of

This product contains aspartame, which is unsuitable for patients with phenylketonuria, an inherited inability to metabolize phenylalanine.

Side Effects

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

Common side effects include:

- somnolence (sleepiness),
- weight gain,
- eosinophilia (increase in the number of eosinophils in the blood),
- elevated prolactin, cholesterol, glucose and triglyceride level,
- glucosuria (excretion of glucose into the urine),
- increased appetite,
- dizziness,

- akathisia (movement disorder; a compelling need to be in constant motion)
- Parkinson's disease (movement abnormalities),
- dyskinesia (impairment of voluntary movement),
- orthostatic hypotension (fall in blood pressure due to sudden movement e.g. standing up from a lying or sitting position)
- anticholinergic effects (description of side effects such as dry mouth and related dental problems, blurred vision)
- temporary increases in liver enzymes
- rash,
- asthenia (physical weakness and loss of strength),
- fatigue
- oedema.

Other uncommon side effects include:

- leucopenia (a reduction in the number of white cells in the blood)
- neutropenia (abnormally few neutrophils in the blood)
- thrombocytopenia (deficiency of platelets in the blood)
- allergy reactions
- diabetes occasionally associated with ketoacidosis (high ketone levels) or coma
- hypothermia (low body temperature)
- seizures
- Neuroleptic malignant syndrome (life-threatening, neurological disorder most often caused by an adverse reaction to neuroleptic or antipsychotic drugs)
- dystonia (a state of abnormal muscle tone), including oculogyration (circular motion of the eyeball)
- tardive dyskinesia (involuntary movements of the face and jaw)
- bradycardia (abnormally slow heart beat)
- heart failure
- thromboembolism (obstruction of a blood vessel)
- inflammation of the pancreas
- sensitive to sunlight, hair loss
- liver disease

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-rhabdomyolysis (breakdown of muscle tissue)
 -urinary problems
 -priapism (abnormal persistent erection of the penis)
 -reproductive system and breast disorders e.g. an abnormal absence of menstruation, breast enlargement, nipple discharge
 -increased creatine phosphokinase, total bilirubin and alkaline phosphatase levels.

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).

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)

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 Onzapin

-Storage

Store below 30°C.

-Disposal

Do not use after the expiry date stated on the label.

Take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

-What it looks like

5mg tablets: Yellow tablets, 6 mm round, biconvex. Markings O

10mg tablets: Yellow tablets, 8 mm round, biconvex. Markings O1

-Ingredients

Active Ingredient

5mg: Each Onzapin orodispersible tablets 5mg contains 5mg olanzapine.

10mg: Each Onzapin orodispersible tablets 10mg contains 10mg olanzapine.

Inactive ingredients

Microcrystalline Cellulose, Crospovidone, Magnesium carbonate heavy, Magnesium Stearate, Silica colloidal anhydrous, Hydroxypropyl cellulose low substituted, aspartame, Avicel CE-15, orange flavour, purified water.

-MAL Number

Onzapin orodispersible 5mg:
MAL17085019AZ

Onzapin orodispersible 10mg:
MAL17085012AZ

Manufacturer

Actavis Ltd.
 BLB016 Bulebel Industrial Estate, Zejtun ZTN 3000, MALTA

Product Registration Holder

DCH Auriga (Malaysia) Sdn. Bhd.
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