Package leaflet: Information for the patient

Olanzapine Mylan 5 mg orodispersible tablets
Olanzapine Mylan 10 mg orodispersible tablets
Olanzapine Mylan 15 mg orodispersible tablets
Olanzapine Mylan 20 mg orodispersible tablets
olanzapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Olanzapine Mylan is and what it is used for

Olanzapine Mylan contains the active substance olanzapine and belongs to a group of medicines called antipsychotics.

Olanzapine Mylan is used to treat 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.

Olanzapine Mylan is used to treat moderate to severe manic episodes, a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with this condition.

2. What you need to know before you take Olanzapine Mylan

Do not take Olanzapine Mylan:
• If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (listed in section 6). 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)**.**

Warnings and precautions
Talk to your doctor before taking Olanzapine Mylan.
• Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olanzapine Mylan tell your doctor.

• 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.
- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- Weight gain has been seen in patients taking Olanzapine Mylan. 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 Mylan. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olanzapine Mylan and regularly during treatment.

• The use of Olanzapine Mylan in elderly patients with dementia is not recommended as it may have serious side effects.

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

• Diabetes
• Heart disease
▪ If you have been told that you have salt imbalances in the blood (especially low levels of potassium or magnesium)
▪ If you were born with prolonged QT interval (seen on ECG, an electrical recording of the heart)
• Liver or kidney disease
• Parkinson's disease
• Epilepsy
• Prostate problems
• A blocked intestine (Paralytic ileus)
• Blood disorders with low blood white blood cell counts (which can be caused by some medicines, radiation therapy, chemotherapy or bone marrow disease)
- If you have been told that you have increased levels of some white blood cells or a disease of the bone marrow in which excessive blood cells are made called myeloproliferative disease

• Stroke or "mini" stroke (temporary symptoms of stroke)

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 Mylan is not for patients who are under 18 years.

Other medicines and Olanzapine Mylan
Tell your doctor if you are taking, have recently taken or might take any other medicines. Especially tell your doctor if you are taking medicines for Parkinson's disease.

Only take other medicines while you are on Olanzapine Mylan if your doctor tells you that you can. You might feel drowsy if Olanzapine Mylan 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 carbamazepine (used as an anti-epileptic or mood stabiliser), fluvoxamine (an antidepressant), or ciprofloxacin (an antibiotic), as it may be necessary to change your Olanzapine Mylan dose.

Also tell your doctor if you:
- smoke (because your dose of olanzapine may need to be adjusted)
- are taking medicines that can alter your heart rhythm such as anti-arrhythmics (like amiodarone, sotalol, quinidine, disopyramide), antibiotics (that belong to the group of macrolides), tricyclic antidepressants.

If you are taking activated charcoal (a chemical substance used to bind other drugs), this should be taken at least 2 hours before or after olanzapine intake because it can interfere with the absorption of olanzapine.

Olanzapine Mylan with alcohol
Do not drink any alcohol if you have been given Olanzapine Mylan as taking it with alcohol may make you feel drowsy.

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 or pharmacist for advice before taking this medicine. You should not be given this medicine when breast-feeding, as small amounts of Olanzapine Mylan 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 or dizzy when you are given Olanzapine Mylan. If this happens do not drive or operate any tools or machines. Tell your doctor.

Olanzapine Mylan contains aspartame
Patients who cannot take phenylalanine should note that Olanzapine Mylan contains aspartame, which is a source of phenylalanine. Maybe harmful for people with phenylketonuria.

3. How to take Olanzapine Mylan

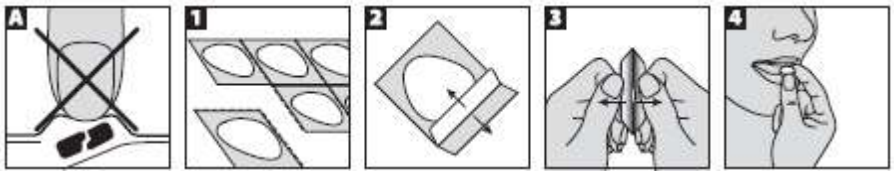
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

You should take your Olanzapine Mylan 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. Olanzapine Mylan orodispersible tablets are for oral use.

Olanzapine Mylan tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.
1. For perforated blisters, hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing. For non-perforated blisters, take care not to peel off the backing of adjacent tablets.
3. Gently push the tablet out.
4. 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, orange juice, apple juice, milk or coffee, and stir. With some drinks, the mixture may change colour and possibly become cloudy. Drink it straight away.



If you take more Olanzapine Mylan than you should
Patients who have taken more Olanzapine Mylan 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. Show the doctor your pack of tablets.

If you forget to take Olanzapine Mylan
Take your tablets as soon as you remember. Do not take two doses in one day.

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

If you suddenly stop taking Olanzapine Mylan 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.

4. Possible 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 (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 (the frequency of this side effect cannot be estimated from the available data).

Other side effects

Very common (may affect more than 1 in 10 people):
• Weight gain.
• Sleepiness.
• Increases in the 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 (may affect up to 1 in 10 people):
• Increases 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 (dyskinesia)
• Constipation.
• Dry mouth.
• Rash.
• Loss of strength.
• Extreme tiredness.
• Water retention leading to swelling of the hands, ankles or feet
- Fever; joint pain
- Sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon (may affect up to 1 in 100 people):
• 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
• 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
• 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)
• 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
• prolonged and/or painful erection.

While taking olanzapine, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations (seeing things that are not there), 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 Olanzapine Mylan may worsen the symptoms and cause hallucinations (seeing, hearing or feeling things that are not there).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

FREEPOST
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL- Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie
E-mail:medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olanzapine Mylan

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and blister/bottle**.**

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

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.

6. Contents of the pack and other information

What Olanzapine Mylan contains

Olanzapine Mylan 5 mg contains 5 mg of olanzapine as the active ingredient.
Olanzapine Mylan 10 mg contains 10 mg of olanzapine as the active ingredient.
Olanzapine Mylan 15 mg contains 15 mg of olanzapine as the active ingredient.
Olanzapine Mylan 20 mg contains 20 mg of olanzapine as the active ingredient.
The other ingredients are mannitol, microcrystalline cellulose, guar gum, crospovidone (type A), magnesium stearate, colloidal anhydrous silica, aspartame (E951) and sodium laurilsulfate.

What Olanzapine Mylan looks like and contents of the pack

Olanzapine Mylan 5 mg is supplied as light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with “M” on one side and “OE1” on other side.

Olanzapine Mylan 10 mg is supplied as light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with “M” on one side and “OE2” on other side.

Olanzapine Mylan 15 mg is supplied as light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with “M” on one side and “OE3” on other side.

Olanzapine Mylan 20 mg is supplied as light yellow to yellow coloured, plain to mottled, round, flat faced, bevelled edged tablets debossed with “M” on one side and “OE4” on other side.

Olanzapine Mylan orodispersible tablets are supplied in non-perforated blisters containing 7, 10, 14, 28, 30, 35, 56, 60, 70, 98, 100 tablets, perforated unit-dose blisters containing (7, 10, 14, 28, 30, 35, 56, 60, 70, 98, 100) x 1 tablets and bottles containing 7, 10, 14, 28, 30, 56, 98, 100, 250, 500 tablets. The bottles also contain a desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

McDermott Laboratories Ltd. T/A Gerard Laboratories.
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland.

Manufacturers:

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft
H-2900 Komarom
Mylan utca 1
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Olanzapin Jenson Pharmaceutical Services Limited 5 mg, 10 mg, 15 mg, & 20 mg Schmelztabletten
Belgium: Olanzapine ODIS Mylan 5 mg, 10 mg, 15 mg, & 20 mg orodispergeerbare tabletten
Cyprus: Olanzapine Jenson Pharmaceutical Services Limited 5 mg, 10 mg, 15 mg, and 20 mg Orodispersible Tablets
Czech Republic: Olanzapin Mylan 5 mg, 10 mg & 15 mg
France: Olanzapine Mylan 5 mg, 10 mg, 15 mg, & 20 mg comprimés orodispersibles
Germany: Olanzapine Mylan 5 mg, 10 mg, 15 mg, & 20 mg Schmelztabletten
Greece: Olanzapine Mylan 5 mg, 10 mg, 15 mg, & 20 mg Orodispersible Tablets
Hungary: Olanzapine Jenson Pharmaceutical Services Limited 5 mg, 10 mg, 15 mg, & 20 mg szajban diszpergalodo tabletta
Ireland: Olanzapine Mylan 5mg, 10mg, 15mg and 20mg Orodispersible Tablets
Poland: Olanzapina Mylan
Portugal: Olanzapina Mylan
Romania: Olanzapină Jenson Pharmaceutical Services Limited 5 mg, 10 mg, 15 mg & 20 mg comprimate orodispersabile
Slovakia: Olanzapin Mylan 5 mg & 10 mg orodispergovateľné tablety
Slovenia: Olanzapin Mylan 5 mg, 10 mg, 15 mg & 20 mg orodisperzibilne tablete
The Netherlands: Olanzapine SmeltTab Mylan 5 mg, 10 mg, 15 mg & 20 mg orodispergeerbare tabletten
United Kingdom: Olanzapine Jenson Pharmaceutical Services Limited 5 mg, 10 mg, 15 mg, and 20 mg Orodispersible Tablets

This leaflet was last revised in September 2014.