Package leaflet: Information for the user

Olanzapine Mylan 2.5 mg film-coated tablets
Olanzapine Mylan 5 mg film-coated tablets
Olanzapine Mylan 7.5 mg film-coated tablets
Olanzapine Mylan 10 mg film-coated tablets
Olanzapine Mylan 15 mg film-coated tablets
Olanzapine Mylan 20 mg film-coated 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 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Olanzapine Mylan contains the active substance olanzapine. 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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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 Mylan has been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

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

Do not take Olanzapine Mylan

- if you are allergic (hypersensitive) to olanzapine, peanut or soya 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 or pharmacist before you take Olanzapine Mylan.

- The use of Olanzapine Mylan 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 Mylan 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 Mylan. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.
- 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.
- 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 know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)

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
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).

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) or ciprofloxacin (an antibiotic) - it may be necessary to change your Olanzapine Mylan dose.

Olanzapine Mylan with alcohol
Do not drink any alcohol if you have been given Olanzapine Mylan as together with alcohol it 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 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 Mylan 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 Mylan. If this happens do not drive or operate any tools or machines. Tell your doctor.

Olanzapine Mylan contains lactose and soya lecithin
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The tablet film-coating contains soya lecithin. If you are allergic to peanut or soya do not take these tablets.

3. How to take Olanzapine Mylan

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 Mylan tablets to take and how long 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 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 tablets are for oral use. You should swallow the Olanzapine Mylan tablets whole with water.

If you take more Olanzapine Mylan than you should

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.

If you forget to take Olanzapine Mylan
Take your tablets as soon as you remember. Do not take a double dose to make up for the forgotten tablet.

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)

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.

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; 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 (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 (ketones in the blood and urine) 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 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 (may affect up to 1 in 1000 people) include 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 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 in 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 Olanzapine Mylan may worsen the symptoms.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton or label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Bottles: After first opening use within 90 days.

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

- The active substance is olanzapine. Each Olanzapine Mylan tablet contains either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg of the active substance. The exact amount is shown on your Olanzapine Mylan tablet pack.
- The other ingredients are:
  (tablet core) lactose monohydrate (see section 2 'Olanzapine contains lactose'), maize starch, preglatinised maize starch, crospovidone type A, magnesium stearate and
  (tablet coating) polyvinyl alcohol, titanium dioxide (E171), talc (E553b), soya lecithin (E322) (see section 2 'Olanzapine Mylan contains soya lecithin'), xanthan gum (E415).

What Olanzapine Mylan looks like and contents of the pack

Olanzapine Mylan 2.5 mg are round, white film-coated tablets with sides that curve outwards, marked with "OZ over 2.5" on one side and "G" on the other side.
Olanzapine Mylan 5 mg are round, white film-coated tablets with sides that curve outwards, marked with "OZ over 5" on one side and "G" on the other side.
Olanzapine Mylan 7.5 mg are round, white film-coated tablets with sides that curve outwards, marked with "OZ over 7.5" on one side and "G" on the other side.
Olanzapine Mylan 10 mg are round, white film-coated tablets with sides that curve outwards, marked with "OZ over 10" on one side and "G" on the other side.

Olanzapine Mylan 15 mg are oval-shaped, white film-coated tablets with sides that curve outwards, marked with “OZ 15” on one side and “G” on the other side.
Olanzapine Mylan 20 mg are oval-shaped, white film-coated tablets with sides that curve outwards, marked with “OZ 20” on one side and “G” on the other side.

Blisters:
Olanzapine Mylan 2.5 mg, 5 mg, 7.5 mg, 15 mg and 20 mg is available in packs containing 10, 28, 30, 35, 56, 70 (2 x 35 multipack) and 70 film-coated tablets.
Olanzapine Mylan 10 mg is available in packs containing 7, 10, 28, 30, 35, 56, 70 (2 x 35) (multipack) and 70 film-coated tablets.

Perforated unit dose blisters:
Olanzapine Mylan 2.5 mg, 15 mg and 20 mg is available in packs containing 28 x 1 film-coated tablets.
Olanzapine Mylan 5 mg and 10 mg is available in packs containing 28 x 1 and 98 x 1 film-coated tablets.
Olanzapine Mylan 7.5 mg is available in packs containing 28 x 1, 56 x 1, 98 x and 100 x 1 film-coated tablets.

Bottles:
Olanzapine Mylan 2.5 mg and 5.0 mg is available in packs containing 250 and 500 film-coated tablets.
Olanzapine Mylan 7.5 mg, 15 mg and 20 mg is available in packs containing 100 film-coated tablets.
Olanzapine Mylan 10 mg is available in packs containing 100 and 500 film-coated tablets.

Marketing Authorisation Holder
Mylan S.A.S., 117 Allée des Parcs, 69800 Saint-Priest, France.

Manufacturer
Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.