PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you take MYLAN OLANZAPINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MYLAN OLANZAPINE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

Schedule 5

PROPRIETARY NAME AND DOSAGE FORM:

MYLAN OLANZAPINE 2,5 mg (tablets)

MYLAN OLANZAPINE 5 mg (tablets)

MYLAN OLANZAPINE 10 mg (tablets)

Olanzapine

1. WHAT MYLAN OLANZAPINE CONTAINS:

MYLAN OLANZAPINE 2,5: Each tablet contains olanzapine 2,5 mg

Each tablet contains lactose monohydrate 80 mg (sugar)

MYLAN OLANZAPINE 5: Each tablet contains olanzapine 5 mg

Each tablet contains lactose monohydrate 160 mg (sugar)

MYLAN OLANZAPINE 10: Each tablet contains olanzapine 10 mg

Each tablet contains lactose monohydrate 320 mg (sugar)

The other ingredients are:

(tablet core): maize starch, pregelatinised maize starch, crospovidone, magnesium stearate and (tablet coating): Opadry white OY-B-28920 containing polyvinyl alcohol part (partially hydrolyzed), titanium dioxide (E171), talc (E553b), lecithin soya (E322), xanthan gum (E415)

2. WHAT MYLAN OLANZAPINE IS USED FOR:

Olanzapine belongs to a group of medicines called antipsychotics.

These medicines help with the effects of some types of mental illness such as:

- schizophrenia
- moderate or severe episodes of mania
- bipolar disorder (manic depression)

3. BEFORE YOU TAKE MYLAN OLANZAPINE:

Do not take MYLAN OLANZAPINE if:

- You are allergic (hypersensitive) to the olanzapine or any of the other ingredients in the **MYLAN OLANZAPINE** tablets

- You have eye problems such as glaucoma (increased pressure in the eye)
- You are a child or an adolescent under the age of 18
- You are pregnant or breast-feeding
- **MYLAN OLANZAPINE** should not be taken by elderly patients with dementia (loss of brain function). This is because there is an increased risk of stroke, or in some cases the risk of death, in elderly patients with dementia

Take special care with MYLAN OLANZAPINE:

Before you take **MYLAN OLANZAPINE** tell your doctor if:

- You have diabetes or have a risk of getting diabetes. **MYLAN OLANZAPINE** may increase blood sugar levels and worsen blood sugar control. Your doctor may check your blood sugar levels regularly while you are taking **MYLAN OLANZAPINE**. Symptoms of high blood sugar (glucose) levels include drinking excessive amounts of water, urinating frequently, eating excessively and feeling weak
- You have a history of seizures (fits)
- You have a liver or kidney disease
- You suffer from a blocked intestine (paralytic ileus)
- You suffer from a prostatic enlargement
- You have any health problems (like heart problems or low blood pressure) or you have had a stroke

- You have a blood problem which means that you bruise more easily or get more infections than usual
- You, or someone else in your family, have had a history of blood clots, as medicines like these have been associated with formation of blood clots
- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- You develop signs and symptoms of tardive dyskinesia (uncontrollable movements, mainly of your face or tongue or slow or difficult movement of limbs (legs, arms)
- **MYLAN OLANZAPINE** must be discontinued and appropriate medical treatment given in case of neuroleptic malignant syndrome (abnormally high body temperature, abnormal muscle movements, which include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain)

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking **MYLAN OLANZAPINE.**

Taking MYLAN OLANZAPINE with food and drink:

You can take **MYLAN OLANZAPINE** with or without food.

Do not drink any alcohol if you have been given **MYLAN OLANZAPINE**. This is because taking alcohol and **MYLAN OLANZAPINE** together may make you feel sleepy.

Pregnancy and breast-feeding:

The safety of **MYLAN OLANZAPINE** during pregnancy and lactation has not been established.

If you are pregnant or breast-feeding your baby while taking MYLAN OLANZAPINE, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor as soon as possible if you are pregnant or think you may be pregnant. You should not take **MYLAN OLANZAPINE** when breast-feeding, as small amounts of **MYLAN OLANZAPINE** can pass into breast milk.

Driving and using machines:

MYLAN OLANZAPINE may cause you to feel drowsy. Do not drive or operate any tools or machinery until you know how **MYLAN OLANZAPINE** affects you.

Important information about some of the ingredients of MYLAN OLANZAPINE:

MYLAN OLANZAPINE tablets contain lactose (milk sugar).

If you know that you cannot tolerate certain sugars, speak to your doctor before taking **MYLAN OLANZAPINE.**

MYLAN OLANZAPINE tablets contain lecithin soya. If you are allergic to peanut or soya, you must not take **MYLAN OLANZAPINE.**

Taking other medicines with MYLAN OLANZAPINE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines the use of MYLAN OLANZAPINE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you are taking any of the following medicines because they might have an interaction with **MYLAN OLANZAPINE:**

- Medicines for Parkinson’s disease

- Medicines for anxiety or depression. This is because taking these medicines with **MYLAN OLANZAPINE** may make you feel sleepy

- Medicines for depression such as fluoxetine or fluvoxamine

- Antifungal medicines such as ketoconazole

- Alcohol

- Levodopa (for treatment of Parkinson’s disease)

- Medicines used for treating high blood pressure

- Medicines for treating heart conditions

- Carbamazepine (for treating epilepsy)

- Antibiotics such as ciprofloxacin

4. HOW TO TAKE MYLAN OLANZAPINE:

Always take **MYLAN OLANZAPINE** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

You should take your **MYLAN OLANZAPINE** tablets once a day following the advice of your doctor. Try to take your tablets at the same each day. It does not matter whether you take them with or without food. **MYLAN OLANZAPINE** tablets are for oral use. You should swallow the **MYLAN OLANZAPINE** tablets whole with water.

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

Do not share medicines prescribed for you with any other person.

If you take more MYLAN OLANZAPINE than you should:

Patients who have taken more **MYLAN 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 even coma. Other symptoms may be: 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take MYLAN OLANZAPINE:

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

If you have any further questions on the use of **MYLAN OLANZAPINE** tablets, ask your doctor or pharmacist.

If you stop taking MYLAN OLANZAPINE:

If you suddenly stop taking **MYLAN OLANZAPINE,** you may be unable to sleep (insomnia), you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability.

Recurrence of your disease symptoms may also occur and symptoms such as involuntary movement disorder (restlessness), continuous muscle contractions, difficulty in movement or slow movement may occur.

Your doctor may suggest you reduce the dose gradually before stopping treatment to prevent these symptoms.

If you have further questions on the use of **MYLAN OLANZAPINE**, ask your doctor or pharmacist.

5. POSSIBLE SIDE-EFFECTS:

MYLAN OLANZAPINE can have side-effects.

If any of the following happen, stop taking **MYLAN OLANZAPINE** and contact your doctor or go to the nearest hospital immediately as **you may need urgent medical attention:**

- A very serious allergic reaction referred to as angioedema can occur. Symptoms include but are not limited to difficulties in breathing, puffiness or swelling around the face, tongue or you have difficulty in swallowing.

  MYLAN OLANZAPINE may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious symptoms such as sore throat, mouth or urinary problems, you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells. It is important to tell your doctor that you are taking **MYLAN OLANZAPINE.**
- An allergic reaction that may include raised lumps (weals), swelling of all layers of the skin and swelling around the mouth or swelling of the throat, severe allergic reaction that may include difficulty in breathing, dizziness and collapse, itching and rash
- Blood clots in the veins, 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.
- Seizures, usually associated with a history of seizures (fits)

- Tardive dyskinesia (uncontrollable movements, mainly of your face and tongue)
- Jaundice (yellowing of the skin and eyes), hepatitis (inflammation of the liver)

Frequent side-effects are:

- blood disorders
- putting on weight
- drowsiness, headache, dizziness, feeling faint, restlessness, tremor, sleeplessness, nervousness, stuttering, muscle stiffness or spasms of face, neck or back), problems with speech
- abnormal rhythms of the heart, slow heart rate
- low blood pressure when standing up from lying down or sitting, increase in blood pressure
- pneumonia
- dry mouth, indigestion or constipation, abdominal pain, diarrhoea, inflammation of the pancreas causing severe stomach pain, fever and sickness

Less frequent side-effects:

- diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma
- anxiety, forgetfulness, aggression

- dry eyes, changes in the lens of the eye with long-term treatment
- stuffy nose, cough, chest disorders
- chest pain
- muscle pain, back pain
- urinary tract infection
- neuroleptic malignant syndrome [a group of symptoms characterized by a raised body temperature (fever), altered mental status, muscle stiffness and spells of dizziness, shortness of breath, a racing heartbeat, fatigue and melancholy (depression)]
- sensitivity to sunlight

Side-effects frequency not known:

- fever
- intentional injury
- 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
- sexual dysfunction such as decreased libido in males and females or erectile dysfunction such as decreased libido in males and females or erectile dysfunction in males
- lowering of normal body temperature
- spasms of the muscle of the eye causing rolling movement of the eye

Some side-effects are only seen when a blood test is taken (these include increase in the amount of liver enzymes or sugar in the blood, decreases in the number of certain types of blood cells)

Contact your doctor before stopping **MYLAN OLANZAPINE** because of side-effects or for any other reason.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not all side-effects reported for MYLAN OLANZAPINE are included in this leaflet. Should your general health worsen while taking MYLAN OLANZAPINE, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORAGE AND DISPOSAL OF MYLAN OLANZAPINE:

MYLAN OLANZAPINE should at all times be kept out of reach of children, as even small doses may be fatal to them.

Store at or below 25 °C. Keep securitainers well closed. Do not remove the blisters from the carton until required for use

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Do not use **MYLAN OLANZAPINE** after the expiry date which is stated on the carton and label/blister.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Ask your pharmacist how to dispose of medicines no longer required.

7. PRESENTATION OF MYLAN OLANZAPINE:

MYLAN OLANZAPINE 2,5 mg: Blister strips in cartons of 28, 35, 56 and 70 tablets per carton. The blister packs comprise of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side.

HDPE bottle pack of 500 and 1000 tablets comprises of round wide mouth white high density polyethylene (HDPE) bottle with white opaque polypropylene (PP) closure with aluminium induction sealing wad along with desiccant (silica gel) canister.

MYLAN OLANZAPINE 5 mg: Blister strips in cartons of 28, 35, 56 and 70 tablets per carton. The blister packs comprise of cold form laminate (aluminium

foil laminated to oriented polyamide on one side and laminated to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side.

HDPE bottle pack of 500 and 1000 tablets comprises of round wide mouth white high density polyethylene (HDPE) bottle with white opaque polypropylene (PP) closure with aluminium induction sealing wad along with desiccant (silica gel) canister.

MYLAN OLANZAPINE 10 mg: Blister strips in cartons of 7, 28, 35, 56 and 70 tablets per carton. The blister packs comprise of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side.

HDPE bottle pack of 500 and 1000 tablets comprises of round wide mouth white high density polyethylene (HDPE) bottle with white opaque polypropylene (PP) closure with aluminium induction sealing wad along with desiccant (silica gel) canister.

8. IDENTIFICATION OF MYLAN OLANZAPINE:

MYLAN OLANZAPINE 2,5 mg: 7,0 mm, round, normal convex, white film-coated tablets debossed “OZ 2,5” on one side and “G” on the other side.

MYLAN OLANZAPINE 5 mg: 8,0 mm, round, normal convex, white film-coated tablets debossed “OZ 5” on one side and “G” on the other side.

MYLAN OLANZAPINE 10 mg: 10,2 mm, round, normal convex, white film-coated tablets debossed “OZ 10” on one side and “G” on the other side.

9. REGISTRATION NUMBERS:

MYLAN OLANZAPINE 2,5: 45/2.6.5/0166

MYLAN OLANZAPINE 5: 45/2.6.5/0167

MYLAN OLANZAPINE 10: 45/2.6.5/0168

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando, Gauteng,

1601

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

25 October 2012