PACKAGE INSERT

SCHEDULING STATUS: **S5**

PROPRIETARY NAME (AND DOSAGE FORM):

MYLAN OLANZAPINE 2,5 (tablets)

MYLAN OLANZAPINE 5 (tablets)

MYLAN OLANZAPINE 10 (tablets)

COMPOSITION:

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)

Excipients: 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)

PHARMACOLOGICAL CLASSIFICATION:

A 2.6.5 Tranquillisers - miscellaneous structures

PHARMACOLOGICAL ACTION:

Pharmacodynamics:

Olanzapine is an atypical antipsychotic, antimanic and mood-stabilising agent having affinity for $5HT_{2A/2C}$, $5HT_3$, $5HT_6$, dopamine D_4, D_3, D_1, D_2, cholinergic muscarinic receptors (M_1 – M_5), alpha-1 (α_1) adrenergic and histamine H1-receptors.

Further studies demonstrate that olanzapine selectively interacts with the mesolimbic system without significantly interacting with the extrapyramidal system. In experimental animals, olanzapine reduces a conditioned avoidance response, a test predictive of antipsychotic activity, at doses below those required to produce catalepsy, a test predictive of motor side-effects. Olanzapine increases response in an “anxiolytic” test. In a single dose (10 mg) PET study in healthy volunteers, olanzapine produced higher $5HT_{2A}$ than dopamine D_2 receptor occupancy.

Olanzapine’s antagonism of muscuranic receptors (M_1 – M_5), may explain its anticholinergic effects. Olanzapine’s antagonism of histamine H_1 receptors may explain the somnolence observed with this medicine. Olanzapine’s antagonism of adrenergic α_1 receptors may explain the orthostatic hypotension observed with this medicine.

Pharmacokinetics:

Olanzapine is well absorbed after oral administration, reaching peak plasma concentrations within 5 to 8 hours. The absorption is not affected by food.

Olanzapine is metabolised in the liver by conjugative oxidative pathways. The major circulating metabolite is the 10-N-glucuronide, which does not pass the blood-brain barrier.

Other metabolites include the N-desmethyl and 2-hydroxymethyl metabolites, neither of which has *in vivo* pharmacological activity. The predominant pharmacologic activity is from the parent compound. After oral administration, the elimination half-life of olanzapine in healthy subjects varies on the basis of age and gender.

	< 65 years	≥ 65 years
Men	29 hours	49 hours
Women	39 hours	55 hours

The mean elimination half-life of olanzapine is about 1,5 times greater in the elderly (≥ 65 years) than in non-elderly subjects (< 65 years) (see **WARNINGS**).

Plasma clearance of olanzapine is higher in smokers (see **Special Precautions**).

The pharmacokinetic characteristics of olanzapine are similar in patients with severe renal impairment and normal subjects, indicating that dosage adjustment based upon the degree of renal impairment is not required. In addition, olanzapine is not removed by haemodialysis. The effect of renal impairment on metabolite elimination has not been studied.

The plasma protein binding of olanzapine is about 93 % over the concentration range of about 7 to about 1000 ng/ml. Olanzapine is bound predominantly to albumin and alpha-1-acid-glycoprotein.

INDICATIONS:

MYLAN OLANZAPINE is indicated for the management of the manifestations of psychotic disorders.

The antipsychotic efficacy of **MYLAN OLANZAPINE** was established in schizophrenic patients in the treatment of positive symptoms (such as delusions, hallucinations, disordered thinking, hostility and suspiciousness and negative symptoms (such as blunted effect, emotional and social withdrawal, poverty of speech).

It is recommended that responding patients be continued on **MYLAN OLANZAPINE** at the lowest dose needed to maintain remission.

Patients should be periodically reassessed to determine the need for the maintenance treatment.

MYLAN OLANZAPINE is also indicated for the treatment of an acute episode of moderate to severe mania and for preventing recurrence of manic or depressive episodes of bipolar disorder.

CONTRA-INDICATIONS:

Hypersensitivity to olanzapine or to any of the components of **MYLAN OLANZAPINE**.

Patients with known risk of narrow-angle glaucoma.

Paediatric patients – Safety and effectiveness in patients under 18 years of age has not been established.

WARNINGS:

- **Hyperprolactinaemia:**

  MYLAN OLANZAPINE elevates prolactin levels and a modest elevation persists during chronic administration.

- **Neuroleptic Malignant Syndrome** (NMS):

  NMS has occurred infrequently in association with **MYLAN OLANZAPINE.**

  NMS is a potentially fatal symptom complex. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of

autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, rhabdomyolysis and acute renal failure. **MYLAN OLANZAPINE** should be discontinued should any of the clinical manifestations of NMS of high fever without additional clinical manifestations of NMS be observed.

- **Tardive dyskinesia:**

  MYLAN OLANZAPINE is associated with a low incidence of treatment emergent dyskinesia. If signs or symptoms of tardive dyskinesia appear in a patient on **MYLAN OLANZAPINE,** a dose reduction or discontinuation of treatment should be considered.

  The risk of tardive dyskinesia increases with long-term exposure and symptoms can temporarily deteriorate or even arise after discontinuation of treatment.

- **Hyperglycaemia and diabetes mellitus:**

  Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with **MYLAN OLANZAPINE**. Patients with an established diagnosis of diabetes mellitus who are started on **MYLAN OLANZAPINE** should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes), who are starting treatment with **MYLAN OLANZAPINE** should be monitored for symptoms of

hyperglycaemia including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycaemia during treatment with **MYLAN OLANZAPINE** should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when **MYLAN OLANZAPINE** was discontinued. However, some patients required continuation of anti-diabetic treatment despite discontinuation of **MYLAN OLANZAPINE**.

- **Seizures:**

  MYLAN OLANZAPINE should be used cautiously in patients who have a history of seizures or who are subject to factors which may lower seizure threshold. Seizures have been reported to occur infrequently in patients treated with **MYLAN OLANZAPINE.** In most cases a history of seizures or risk factor for seizures was reported.

- **Hepatic Impairment:**

  Caution should be exercised in patients with signs and symptoms of hepatic impairment. In patients with pre-existing conditions associated with limited hepatic functional reserve and in patients who are being treated with potentially hepatotoxic medicines. Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

  A starting dose of 5 mg should be considered for patients with moderate hepatic impairment.

- Caution should be exercised in dosing the elderly, especially if there are other factors that might additively influence medicine metabolism and/or pharmacodynamic sensitivity (see **Special Precautions**).

- **Discontinuation reactions:**

  Discontinuation reactions may occur, usually within a week of discontinuing **MYLAN OLANZAPINE**. These reactions may consist of a cholinergic syndrome (diaphoresis, diarrhoea, sialorrhoea, nausea and vomiting, anxiety, agitation, insomnia and tremor). **MYLAN OLANZAPINE** should therefore be gradually discontinued.

- In elderly patients with dementia-related psychosis, the efficacy of **MYLAN OLANZAPINE** has not been established. In placebo-controlled clinical trials of elderly patients with dementia-related psychosis, the incidence of death in olanzapine-treated patients was significantly greater than placebo-treated patients (3,5 % vs 1,5 %) respectively). Abnormal gait and falls were very common (>10 %), urinary incontinence and respiratory infection were common, and there was an increased incidence in cerebrovascular incidents, including stroke. Risk factors that may predispose this patient population to increased mortality when treated with **MYLAN OLANZAPINE** include age ≥ 80 years, sedation, concomitant use of benzodiazepines, or presence of pulmonary conditions (e.g. pneumonia, with or without aspiration).

INTERACTIONS:

Potential interactions affecting **MYLAN OLANZAPINE**:

Since olanzapine is metabolised by CYP1A2, substances that specifically induce, inhibit or act as a substrate to this isoenzyme may affect the pharmacokinetics of olanzapine.

Concomicant use of MYLAN OLANZAPINE:

- Other centrally acting agents – Given the primary CNS effects of olanzapine, caution should be exercised when **MYLAN OLANZAPINE** is taken in combination with other centrally acting agents (especially those that can cause CNS depression) and alcohol.

- **Fluoxetine** – in combination with **MYLAN OLANZAPINE** may cause an increase in the maximum concentration of olanzapine and a decrease in olanzapine clearance. The effect of repeat dosage of **MYLAN OLANZAPINE** and higher dosages has not been evaluated. Combination therapy is not advised.

- **Levodopa** – **MYLAN OLANZAPINE** exhibits *in vitro* dopamine antagonism and may antagonise the effects of levodopa and dopamine agonists.

- **Antihypertensive agents** – **MYLAN OLANZAPINE** may enhance the effects of certain antihypertensive agents because of the potential for inducing hypotension.

Olanzapine has α_1 adrenergic antagonist activity. Caution should be exercised in patients who receive treatment with medicinal products that can lower blood pressure by mechanisms other than α_1 adrenergic antagonism.

- **Medicines that increase the QTc interval** – Increase in the QTc interval has been reported. Caution should be exercised when **MYLAN OLANZAPINE** is prescribed together with other medicines known to increase the QTc interval, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia.

- **Antacids** – Single doses of antacid (aluminium, magnesium) or cimetidine do not affect the oral bioavailability of olanzapine. However, the concomitant administration of activated charcoal reduces the oral bioavailability of olanzapine by 50 to 60 % and should be taken at least 2 hours before or after **MYLAN OLANZAPINE.**

- **Inducers of CYP1A2** – The metabolism of olanzapine may be induced by concomitant smoking or by carbamazepine therapy causing slightly to moderately lower olanzapine plasma levels.
  Clinical monitoring is recommended and an increase of the **MYLAN OLANZAPINE** dose may be considered, if necessary.

- **Inhibitors of CYP1A2** – Known potent inhibitors of CYP1A2 activity may

decrease olanzapine clearance. Fluvoxamine, a specific CYP1A2 inhibitor, has been shown to significantly inhibit the metabolism of olanzapine.
A lower starting dose of **MYLAN OLANZAPINE** should be considered in patients who are using fluvoxamine or any other CYP1A2 inhibitors, such as ciprofloxacin or ketoconazole. A decrease in the dose of **MYLAN OLANZAPINE** should be considered if treatment with an inhibitor of CYP1A2 is initiated.

- **Potential for MYLAN OLANZAPINE to affect other medicines** – No inhibition of the metabolism of imipramine/desipramine (P450-CYP2D6 or P450-CYP3A/1A2, warfarin (P450-CYP2C9), theophylline (P450-CYP1A2) or diazepam (P450-CYP3A4 and P450-CYP2C19) is evident. **MYLAN OLANZAPINE** does not interact when co-administered with lithium or biperiden.

PREGNANCY AND LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

Oral dosing: Psychotic disorders:

MYLAN OLANZAPINE tablets should be administered on a once-a-day schedule without regard to meals, generally beginning with an initial dose of 5 to 10 mg/day, with a target dose of 10 mg/day within several days.

In order to evaluate efficacy and guard against side-effects increases should not be considered before one week, since steady state for olanzapine would not be achieved for approximately one week. The dose range is from 5 mg to 20 mg per day. Increasing the dose over the routine daily dose of 10 mg is advised only after appropriate clinical assessment.

Acute mania in bipolar disorder:

MYLAN OLANZAPINE should be administered on a once-a-day schedule without regard to meals, generally beginning with a 10 mg. Dosage adjustments within the dose range of 5 mg to 20 mg per day, if indicated, should generally occur at intervals of not less than 24 hours.

Preventing recurrence in bipolar disorder:

The recommended starting dose is 10 mg per day. For patients who have been receiving **MYLAN OLANZAPINE** for treatment of manic episode, continue therapy for preventing recurrence at the same dose.

An increase to a dose greater than the recommended starting dose, within the range of 5 mg to 20 mg per day, is advised only after appropriate clinical assessment and should generally occur at intervals of not less than 24 hours.

The safety of doses above 20 mg/day has not been evaluated in clinical trials.

Gradual tapering of the dose should be considered when discontinuing **MYLAN OLANZAPINE** (see **WARNINGS**).

Increasing the dose over the routine daily dose of 10 mg is advised only after appropriate clinical assessment.

A 5 mg starting dose should be considered for patients with hepatic impairment and may also be considered for the elderly patient.

The safety of doses above 20 mg/day has not been evaluated in clinical trials. Improvement in the patient's clinical condition may take several days to weeks. Patients should be closely monitored during this period.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Blood and lymphatic system disorders:

Frequent: Eosinophilia, leucopenia, thrombocytopenia, neutropenia

Immune system disorders:

Less frequent: Allergic reactions (e.g. anaphylactoid reaction, angioedema, pruritus, urticaria)

Metabolic and nutritional disorders:

Frequent: Weight gain, increased appetite

Less frequent: Hyperglycaemia, hypertriglyceridaemia, development or exacerbation of diabetes, diabetic ketoacidosis, diabetic coma

Psychiatric disorders:

Less frequently: Personality disorder, amnesia, anxiety, euphoria, hostility

Nervous system disorders:

Frequent: Somnolence, headache, dizziness, akathisia, Parkinsonism, asthenia, agitation, tremor, nervousness, myoclonus, insomnia, stuttering, extrapyramidal effects (neck rigidity, muscle spasms of face, neck or back), dystonia, abnormal gait, speech disorder

Less frequent: Dyskinesia, movement disorder, articulation impairment, hypertonia, neuroleptic malignant syndrome, tardive dyskinesia

Frequency unknown: Seizures

Eye disorders:

Less frequent: Amblyopia, blepharitis, corneal lesion

Cardiac disorders:

Less frequent: Chest pain, bradycardia, tachycardia, changes in ECG parameters, ventricular tachydysrhythmias

Vascular disorders:

Frequent: Orthostatic hypotension, hypotension, peripheral oedema

Respiratory, thoracic and mediastinal disorders:

Frequent: Pneumonia

Less frequent: Rhinitis, cough, pharyngitis.

Gastrointestinal disorders:

Frequent: Dry mouth, constipation, abdominal pain, pancreatitis

Hepato-biliary disorders:

Frequent: Transient asymptomatic elevations of hepatic transaminases (ALT, AST)

Frequency unknown: Hepatitis, jaundice

Skin and subcutaneous tissue disorders:

Less frequent: Photosensitivity disorders

Frequency unknown: Rash, alopecia

Musculoskeletal, connective tissue and bone disorders:

Less frequent: Extremity pain (other than joint), joint pain, back pain, rhabdomyolysis

Reproductive system and breast disorders:

Frequency unknown: Priapism, premenstrual syndrome

Frequency unknown: Fever, intentional injury

Investigations:

Elevated prolactin levels, high creatine phosphokinase, decreased erythrocyte count, haematocrit, haemoglobin, leucocyte count, lymphocytes, thrombocytes and platelets, increased MCHC, lymphocytes, monocytes and eosinophils, decreased bicarbonate, calcium phosphorous, albumin and total protein, increased chloride, GGT and phosphorous.

Special Precautions:

During antipsychotic treatment, improvement in the patient's clinical condition may take several days to some weeks. Patients should be closely monitored during this period.

Transaminase elevations:

Transient elevations of liver transaminases (ALT, AST) have been observed. Caution should therefore be exercised in patients with elevated ALT and/or AST, in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve and in patients who are being treated with potentially hepatotoxic agents. In the event of

elevated ALT and/or AST during treatment, follow-up should be organised and dose reduction should be considered. In cases when hepatitis has been diagnosed**, MYLAN OLANZAPINE** treatment should be discontinued.

Concomitant illnesses:

Clinical experience with **MYLAN OLANZAPINE** in patients with concomitant illnesses is limited. As **MYLAN OLANZAPINE** has demonstrated anticholinergic activity *in vitro,* caution is advised when prescribing for patients with symptomatic prostatic enlargement, narrow-angle glaucoma or paralytic ileus and related conditions. **MYLAN OLANZAPINE** has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from pre-marketing clinical studies. Because of the risk of orthostatic hypotension with **MYLAN OLANZAPINE**, caution should be observed in cardiac patients.

There is an increased prevalence of diabetes amongst patients with schizophrenia. Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases during **MYLAN OLANZAPINE** treatment. In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for developing diabetes mellitus (see **WARNINGS – Hyperglycaemia and diabetes mellitus).**

Cerebrovascular adverse events (CVAE), including stroke, in elderly patients with dementia:

Cerebrovascular adverse events (e.g. stroke, transient ischaemic attack), including fatalities, were reported in trials of olanzapine in elderly patients with dementia-related psychosis.

In placebo-controlled studies, there was a higher incidence of CVAE in patients treated with olanzapine compared to patients treated with placebo. All patients who experienced a cerebrovascular event had pre-existing risk factors known to be associated with an increased risk for a CVAE (e.g. history of previous CVAE or transient ischaemic attack, hypotension, cigarette smoking and presented with concurrent medical conditions and/or concomitant medications having a temporal association with CVAE. **MYLAN OLANZAPINE** is not approved for the treatment of patients with dementia-related psychosis.

Body temperature regulation:

Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic medicines. Appropriate care is advised when prescribing **MYLAN OLANZAPINE** for patients who will be experiencing conditions which may contribute to an elevation in core body temperature.

Dysphagia:

Oesophageal dysmotility and aspiration have been associated with antipsychotic medicines. **MYLAN OLANZAPINE** should be used with caution in patients at risk for aspiration pneumonia.

Suicide:

The possibility of suicide attempt is inherent in schizophrenia and close supervision of high risk patients should accompany **MYLAN OLANZAPINE** treatment.

Elderly patients:

In clinical studies, in general, there is no indication of any different tolerability of olanzapine in the elderly compared to younger adults. The presence of factors that might decrease pharmacokinetic clearance or increase the pharmacodynamic response to **MYLAN OLANZAPINE,** should lead to consideration of a lower starting dose.

Patients with haematological disorders:

Caution should be exercised when using **MYLAN OLANZAPINE** in patients with low leucocyte and/or neutrophil counts due to any reason, patients with a history of medicine-induced bone marrow depression/toxicity, patients with bone marrow depression caused by concomitant illness, radiation therapy or chemotherapy and in patients with hypereosinophilic conditions or with myeloproliferative disease.

Orthostatic hypotension:

MYLAN OLANZAPINE may induce orthostatic hypotension associated with dizziness, tachycardia and in some patients syncope, especially during the initial treatment period.

Plasma clearance of olanzapine is higher in smokers.

The combined effects of age, smoking and gender could lead to substantial pharmacokinetic differences. The clearance in young smoking males, for example, may be 3 times higher than that in elderly non-smoking females. Dosing modification may be necessary in patients who exhibit a combination of factors that may result in slower metabolism of olanzapine.

MYLAN OLANZAPINE tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take **MYLAN OLANZAPINE.**

MYLAN OLANZAPINE tablets contain lecithin soya. Patients who are allergic to peanut or soya, should not take **MYLAN OLANZAPINE.**

Effects on ability to drive and use machines:

MYLAN OLANZAPINE may cause somnolence. Patients should be cautioned about operating hazardous machinery including motor vehicles until they are reasonably certain that **MYLAN OLANZAPINE** therapy does not affect them adversely.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Signs and symptoms:

Frequent symptoms of **MYLAN OLANZAPINE** overdose include tachycardia, agitation/aggressiveness, dysarthria, various extrapyramidal symptoms and reduced level of consciousness ranging from sedation to coma.
Other medically significant sequelae of **MYLAN OLANZAPINE** overdose will include delirium, convulsions, possible neuroleptic malignant syndrome, respiratory depression, aspiration, hypertension or hypotension, cardiac dysrhythmias and cardiopulmonary arrest. Fatal outcomes have been reported for acute overdoses as low as 450 mg but survival has also been reported following acute overdose of 1 500 mg.

Treatment:

The possibility of multiple medicine involvement should be considered. In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. The possibility of obtundation, seizures of dystonic reaction of the head and neck following overdose, may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible dysrhythmias.

There is no specific antidote to **MYLAN OLANZAPINE;** therefore, appropriate symptomatic and supportive measures should be initiated. Hypotension and

circulatory collapse should be treated with appropriate measures, such as intravenous fluids and/or sympathomimetic agents. Induction of emesis is not recommended. Do not use epinephrine (adrenaline), dopamine or other sympathomimetics with ß-agonist activity, since β-stimulation may worsen hypotension in the setting of **MYLAN OLANZAPINE**-induced α-blockade. Close medical supervision and monitoring should continue until the patient recovers.

IDENTIFICATION:

MYLAN OLANZAPINE 2,5: 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: 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: 10,2 mm, round, normal convex, white film-coated tablets debossed “OZ 10” on one side and “G” on the other side.

PRESENTATION:

MYLAN OLANZAPINE 2,5: 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: 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: 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.

STORAGE INSTRUCTIONS:

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

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

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando, Gauteng,

1601

DATE OF PUBLICATION OF THE PACKAGE INSERT:

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