

## OLANZAMED® Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

### Information about OLANZAMED

OLANZAMED is available as 5 mg, 10 mg and 20 mg tablets for oral administration containing respectively 5 mg, 10 mg and 20 mg of olanzapine.

Excipients are: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium and talc.

Olanzapine is an antipsychotic agent. Its therapeutic activity is mediated through a combination of dopamine and serotonin Type 2 (5HT<sub>2</sub>) receptor antagonism.

OLANZAMED is indicated in the following conditions:

- Treatment of schizophrenia in adults and adolescents over 13 years of age.
- As monotherapy in the acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder in adults.
- As monotherapy in the acute treatment of manic or mixed episodes associated with bipolar I disorder in adolescents over 13 years of age.
- As adjunctive therapy to lithium or valproate for the treatment of manic or mixed episodes associated with bipolar I disorder in adults.
- In combination with fluoxetine for the treatment of Depressive Episodes associated with Bipolar I Disorder in adults and adolescents over 10 years of age.
- In combination with fluoxetine for the treatment of resistant depression in adults.

This medicine may be used to treat other conditions as well.

### The way to take OLANZAMED

Take OLANZAMED as directed by your doctor. Do not discontinue the treatment without consulting your doctor. Dosage is individualized through consideration of severity of symptoms. OLANZAMED can be given without regard to meals.

OLANZAMED is administered on a once-a-day schedule. The therapy is initiated at a low dose and then increased gradually and maintained to the most effective and well tolerated dosage.

Dosage adjustments, if indicated, can be made according to efficacy, tolerability, and to the condition under treatment.

The usual recommended dosages are:

Indication	Initial Dose	Dose range	Maintenance dose
Treatment of schizophrenia in adults	5-10 mg once daily; Target: 10 mg/day within several days.	10 mg to 15 mg once daily	10 mg to 20 mg once daily
Treatment of schizophrenia in adolescents over 13 years of age	2.5 or 5 mg once daily; Target: 10 mg/day	2.5 mg to 20 mg once daily	Efficacy has not been evaluated
Bipolar I disorder (manic or mixed episodes) in adults as monotherapy	10 mg or 15 mg once daily	5 mg to 20 mg once daily	5 mg to 20 mg once daily
Bipolar I disorder (manic or mixed episodes) in adults	10 mg once daily	5 mg to 20 mg once	-

as adjunctive treatment to lithium or valproate		daily	
Bipolar I disorder (manic or mixed episodes) in adolescents over 13 years of age	2.5 or 5 mg once daily; Target: 10 mg/day	2.5 mg to 20 mg once daily	Efficacy has not been evaluated
Depressive Episodes associated with Bipolar I Disorder in adults in combination with fluoxetine	5 mg of oral olanzapine and 20 mg of fluoxetine once daily in the evening	Olanzapine 5 mg to 12.5 mg and fluoxetine 20 mg to 50 mg	-
Depressive Episodes associated with Bipolar I Disorder in adolescents over 10 years of age in combination with fluoxetine	2.5 mg of oral olanzapine and 20 mg of fluoxetine once daily in the evening.	Safety of co-administration of doses above 12 mg olanzapine with 50 mg fluoxetine has not been evaluated in pediatrics.	-
Treatment of Resistant Depression in adults in combination with fluoxetine	5 mg of oral olanzapine and 20 mg of fluoxetine once daily in the evening.	Olanzapine 5 mg to 20 mg and fluoxetine 20 mg to 50 mg	-

#### **Duration of treatment**

The duration of treatment will be decided by your doctor. Do not discontinue therapy of your own accord even if you feel better; you may require continuous treatment for quite some time. You should be periodically reassessed to determine the need for maintenance therapy with an appropriate dose.

#### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

#### **In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

#### **Contraindications**

This drug is contraindicated in patients with a known hypersensitivity to any of the components.

#### **Precautions**

- This drug should be used with caution in patients with hepatic impairment, prostatic hypertrophy, narrow angle glaucoma, a history of paralytic ileus, breast cancer, Alzheimer's disease, Parkinson's disease, diabetes mellitus, and history of seizures or with conditions that potentially lower the seizure threshold.
- This drug is not approved for the treatment of patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death and of cerebrovascular adverse events.
- Possibility of a suicide attempt is inherent in schizophrenia and in bipolar I disorder, and close supervision of high risk patients should accompany drug therapy.
- Inform your doctor at once if a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness occurs.
- Patients taking this medication should undergo fasting blood glucose testing and blood lipid testing at the beginning of and periodically during treatment; patients should also receive a regular monitoring of weight.

- Patients with a history of a clinically significant low white blood cell count or drug induced leukopenia/neutropenia should have their complete blood count monitored frequently.
- This drug should be discontinued if signs and symptoms of tardive dyskinesia (irreversible, involuntary, dyskinetic movements) appear.
- It is advisable to get up slowly when rising from a lying or sitting position to avoid dizziness. This drug must be used with caution in patients with known cardiovascular disease, cerebrovascular disease, and with conditions that predispose to hypotension. It is recommended that blood pressure is measured periodically in patients over 65 years.
- Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. This drug is not recommended during lactation.

#### **Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently. Avoid the use of alcohol with this drug. Caution should be used when olanzapine is taken in combination with other centrally acting drugs. You may require dosage adjustment or special monitoring during treatment if you are taking any of the following medicines: antihypertensive medications, carbamazepine, fluvoxamine, omeprazole, rifampicin, diazepam, levodopa, and dopamine agonists.

#### **Adverse reactions**

The most common reported adverse reactions include: orthostatic hypotension, lack of energy, pain in the arms or legs, dry mouth, increased appetite, weight gain, hyperglycemia, high fat levels in the blood, sleepiness, tremor, dizziness, headache, abdominal pain, constipation, changes in behavior, and restlessness.

Other reported adverse reactions include: Neuroleptic Malignant Syndrome (high fever, excessive sweating, rigid muscles, confusion, changes in breathing, in heart beat, and in blood pressure), Tardive Dyskinesia (a movement disorder), problems with Control of Body Temperature, cerebrovascular events, difficulty swallowing, seizures, blood disorders, increase in prolactin level and in liver enzymes.

Please inform your doctor if any side effect appears or becomes bothersome.

#### **Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

#### **Pack Presentation**

OLANZAMED, olanzapine 5 mg, pack of 30 tablets

OLANZAMED, olanzapine 10 mg, pack of 30 tablets

OLANZAMED, olanzapine 20 mg, pack of 30 tablets

**Revision date: 09/2013**

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