

## **Prescribing Information:**

**Description:** Pericam® tablet contains Olanzapine. Olanzapine is an antipsychotic agent and has affinities for serotonin 5-HT<sub>2</sub>, 5-HT<sub>3</sub>, 5-HT<sub>6</sub>; dopamine D<sub>1</sub>, D<sub>2</sub>, D<sub>3</sub>, D<sub>4</sub>, D<sub>5</sub>; cholinergic muscarinic receptors M<sub>1</sub>-M<sub>5</sub>; α<sub>1</sub> adrenergic; and histamine H<sub>1</sub> receptors. The mechanism of action of Olanzapine, as like other drugs having efficacy in schizophrenia, is unknown. However, it has been proposed that this drug's efficacy in schizophrenia is mediated through a combination of dopamine and serotonin type 2 (5-HT<sub>2</sub>) antagonism. 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 not mutagenic or clastogenic as well as not carcinogenic.

**Indication:** Pericam® is indicated for the acute and maintenance treatment of schizophrenia and related psychoses where positive symptoms (e.g. delusions, hallucinations, disordered thinking, hostility and suspiciousness) and/or negative symptoms (e.g. flattened affect, emotional and social withdrawal, poverty of speech) are prominent. Pericam® is indicated for the treatment of acute mania or mixed episodes in bipolar disorder, with or without psychotic features and with or without a rapid cycling course.

**Dosage and Administration:** The recommended starting dose for Pericam® is 10 mg/day, administered as a single daily dose without regard to meals. Olanzapine Orally Disintegrating Tablets should be taken by mouth, immediately after opening the blister pack, with or without food. Blister packs should be opened in dry hand. The foil on the blister pack should be peeled back to remove the tablet. The tablet should be placed on tongue to get dissolved quickly and swallowed with saliva. Olanzapine Orally Disintegrating Tablets may be taken with or without water. Daily dosage may subsequently be adjusted on the basis of individual clinical status within the range of 5-20 mg daily. An increase to a dose greater than the routine therapeutic dose of 10 mg/day i.e. to a dose of 15 mg/day or greater, is recommended only after appropriate clinical reassessment. Children: Olanzapine has not been studied in subjects under 18 years of age. Elderly patients (age 65 and over); starting dose 5 mg/day. Patients with hepatic and/or renal impairment: starting dose 5 mg/day. When more than one factor is present which might result in slower metabolism (female gender, geriatric age, non-smoking status), consideration should be given to decreasing the starting dose. Dose escalation, when indicated, should be conservative in such patients.

**Contraindication:** Olanzapine is contraindicated in those patients with a known hypersensitivity to any ingredient of the product as well as in patients with known risk for narrow angle glaucoma.

**Precaution:** Concomitant illness: Caution is advised when prescribing Olanzapine for patients with prostatic hypertrophy, or paralytic ileus and related conditions. All antipsychotic medicines, including Olanzapine must be discontinued in patients with Neuroleptic Malignant Syndrome (NMS), or with unexplained high fever without additional clinical manifestations of NMS. Olanzapine should be used cautiously in patients who have a history of seizures or have conditions associated with seizures. Olanzapine should be used cautiously in patients with low leukocyte and/or neutrophil counts for any reason, drug induced bone marrow depression/toxicity caused by radiation therapy or chemotherapy, hypereosinophilic conditions, impaired hepatic function, and patients using hepatotoxic medicines, centrally acting drug and medicines known to increase QT interval, especially in elderly. Patients should be cautioned about operating hazardous machinery, including motor vehicles. Drug Interaction: Drugs that induce CYP1A2 or glucuronyl transferase enzymes (omeprazole, rifampicin), inhibitor of CYP1A2 (fluvoxamine), centrally acting drugs, antihypertensive agents.

**Adverse Effect:** Frequent (>10%): somnolence and weight gain. Occasional (1-10%): dizziness, asthenia, akathisia, increased appetite, peripheral oedema, orthostatic hypotension, and mild, transient anticholinergic effects including constipation and dry mouth; transient, asymptomatic elevations of hepatic transaminases, ALT, AST, Rare (0.1-1%): Photosensitivity reaction and bradycardia.

**Use in Pregnancy and Lactation:** Olanzapine should be used in pregnancy only if the potential benefits justify the potential risk to the foetus. So, patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with Olanzapine. There is no report to show teratogenicity. Patients should not breast feed if they are taking Olanzapine.

**Commercial Pack:** Pericam® 5 tablet: Box containing 100 tablets in 10 x 10's blister strips. Each oro-dispersible tablet contains Olanzapine INN 5 mg. Pericam® 10 tablet: Box containing 100 tablets in 10 x 10's blister strips. Each oro-dispersible tablet contains Olanzapine INN 10 mg.

Manufactured by  
Beximco Pharmaceuticals Ltd.  
TONGI, Bangladesh

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