Deprex®

Olanzapine

COMPOSITION
Deprex® 5 Tablet: Each film coated tablet contains Olanzapine EP 5 mg.
Deprex® 10 Tablet: Each film coated tablet contains Olanzapine EP 10 mg.

PHARMACOLOGY
Olanzapine is an antipsychotic agent and has affinities for serotonin 5HT2A/2C, 5HT3, 5HT6; dopamine D1, D2, D3, D4, D5; cholinergic muscarinic receptors M1-M5; A1 adrenergic; and histamine H1 receptors. The mechanism of action of Olanzapine, as with 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 (5HT2) 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
Deprex® is indicated for the acute and maintenance treatment of schizophrenia and related psychoses where positive symptoms (e.g. delusions, hallucinations, disordered thinking, hostility and sEPiciousness) and/or negative symptoms (e.g. flattened affect, emotional and social withdrawal, poverty of speech) are prominent.
Deprex® is indicated for the treatment of acute manic 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 **Deprex®** is 10 mg/day, administered as a single daily dose without regard to meals. 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 is 5 mg/day.
Patients with hepatic and/or renal impairment: starting dose is 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 olanzapine as well as in patients with known risk for narrow-angle glaucoma.

PRECAUTION
Concomitant illness: Olanzapine in patients with concomitant illness is limited, caution is advised when prescribing for patients with prostatic hypertrophy, or paralytic ileus and related conditions.
Neuroleptic Malignant Syndrome (NMS): If a patient develops signs and symptoms indicative of NMS, or presents with unexplained high fever without additional clinical manifestations of NMS, all antipsychotic medicines, including olanzapine must be discontinued.
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 know to increase QT interval, especially in the elderly.
Patients should be cautioned about operating hazardous machinery, including motor vehicles.

This product contains Lactose.

DRUG INTERACTION
Drugs that induce CYP1A2 or glucoronyl 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.

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 teratogenecity. Patients should not breastfeed if they are taking Olanzapine.

STORAGE CONDITION
Store below 30°C. Protect from light and moisture.
Keep out of the reach of children.

HOW SUPPLIED
Deprex® 5 Tablet: Box containing 3 x 10 / 5 x 10 / 10 x 10 tablets in blister pack.
Deprex® 10 Tablet: Box containing 3 x 10 / 5 x 10 / 10 x 10 tablets in blister pack.

SQUARE