

# Xytrex<sup>®</sup>

Olanzapine 5mg & 10mg tablet

## **Description**

Xytrex<sup>®</sup> is a preparation of Olanzapine which is an atypical antipsychotic agent. Olanzapine may work by blocking receptors for several neurotransmitters in the brain. It has a greater affinity for serotonin 5HT<sub>2</sub> receptor and has lesser affinities for dopamine (D<sub>1</sub>, D<sub>2</sub>, D<sub>3</sub>, D<sub>4</sub> & D<sub>5</sub>); cholinergic muscarinic (M<sub>1</sub>-M<sub>5</sub>); adrenergic ( $\alpha$ <sub>1</sub>); and histamine (H<sub>1</sub>) receptors.

## **Indication and usage**

Xytrex<sup>®</sup> is indicated for the treatment of schizophrenia; treatment of acute mixed or manic episodes with bipolar I disorder; in combination with lithium or valproate for short-term treatment of acute mixed or manic episodes associated with bipolar I disorder; maintenance treatment of bipolar patients on monotherapy after achieving a responder status for an average duration of 2 wk.

## **Dosage and administration**

### **Adults**

*Schizophrenia:* starting dose: 10 mg per day

*Manic episode:* starting dose: 15 mg once daily in monotherapy or 10 mg once daily in combination therapy

*Preventing recurrence in bipolar disorder:* starting dose: 10 mg per day. For patients who have been receiving Xytrex<sup>®</sup> for treatment of manic episode, therapy should be continued for preventing recurrence at the same dose.

*Maintenance dose range for Schizophrenia, mania and preventing recurrence in bipolar disorder:*

5-20 per day.

### **Children and adolescents**

Olanzapine is not recommended for children and adolescents below 18 years of age.

### **Elderly**

A lower starting dose (5 mg per day) is not routinely indicated, but should be considered for those aged 65 years and above when clinical factors warrant.

### **Patients with renal and/or hepatic impairment**

A lower starting dose (5 mg) should be considered for such patients. In cases of moderate hepatic insufficiency (cirrhosis, Child-Pugh class A or B), the starting dose should be 5 mg and should be increased with caution.

### **Use in pregnancy and lactation**

Olanzapine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Patients taking Olanzapine should be advised not to breast-feed.

## Precautions

Olanzapine may cause somnolence and dizziness, so patients should be cautioned about operating machinery, including motor vehicles. Patients with clinically important prostatic hypertrophy, CV disease, conditions that predispose patients to hypotension (eg, dehydration, hypovolemia), narrow-angle glaucoma, a history of paralytic ileus, seizures should use Olanzapine with caution.

## Side effects

Common: weight gain, dizziness, extrapyramidal symptoms (usually mild and transient), drowsiness, speech difficulty, exacerbation of Parkinson's disease, abnormal gait, hallucinations, akathisia, asthenia, fatigue, increased appetite, eosinophilia; Less Common: bradycardia, QT interval prolongation, photosensitivity. Rare: seizures, leucopenia, rash; Very Rare: thromboembolism, hypercholesterolaemia, hypothermia, urinary retention, thrombocytopenia, neutropenia, rhabdomyolysis, hepatitis, pancreatitis and alopecia

## Drug interactions

Drugs which inhibit or act as a substrate to Cytochrome P<sub>450</sub> isoenzymes or glucoronyl transferase enzymes (omeprazole, rifampicin, fluvoxamine), dopamine agonists, antiarrhythmics (methyl dopa, guanethidine, procainamide, quinidine), tricyclic antidepressants (fluvoxamine, fluoxetine), antiepileptics (phenobarbitone, carbamazepine, phenytoin), terfenadine.

## Contraindications

Olanzapine is contra-indicated in patients with known hypersensitivity to the active substance or to any of the excipients and also contra-indicated in narrow-angle glaucoma.

## Overdose

Common symptoms include tachycardia, agitation/aggressiveness, various extrapyramidal symptoms, and reduced level of consciousness ranging from sedation to coma. Other symptoms include delirium, convulsion, respiratory depression, aspiration, hypertension or hypotension, cardiac arrhythmias, and cardiopulmonary arrest.

## Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

## Presentation

Xytrex<sup>®</sup>5 tablet: Each tablet contains Olanzapine INN 5 mg.

Xytrex<sup>®</sup>10 tablet: Each tablet contains Olanzapine INN 10 mg.

## Packaging

Xytrex<sup>®</sup>5 tablet: Carton of 50 tablets in blister

Xytrex<sup>®</sup>10 tablet: Carton of 50 tablets in blister

® Registered Trade Mark



ACI Limited

Narayanganj, Bangladesh.