

**Olanzapine Cas No. : 132539-06-1**

This medication is used to treat certain mental/mood conditions (schizophrenia, bipolar mania). It works by helping to restore the balance of certain natural chemicals in the brain (neurotransmitters).

Active Pharmaceuticals Ingredients Manufacturers



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# Taj Pharmaceuticals Ltd.

## Olanzapine

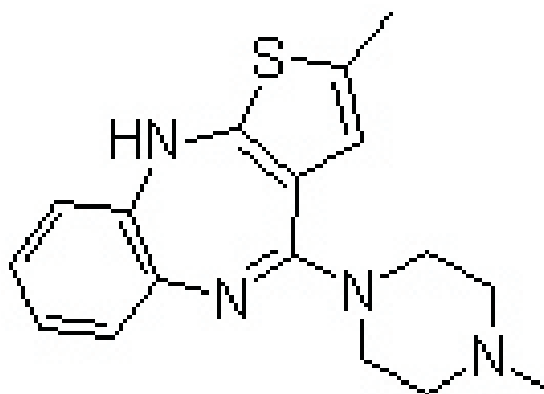
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**Systematic (IUPAC) name**

2-Methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b][1,5]benzodiazepine; Lanzac; Zyprexa

**Chemical data**

Molecular Formula C<sub>17</sub>H<sub>20</sub>N<sub>4</sub>S  
 Molecular Weight 312.43  
 CAS Registry Number 132539-06-1  
 Formula C<sub>17</sub>H<sub>20</sub>N<sub>4</sub>S  
 Mol. mass 312.439  
 SMILES eMolecules & PubChem

**Pharmacokinetic data**

Bioavailability ?  
 Metabolism Hepatic  
 Half life 21–54 hours

**DOSAGE**

The usual oral dose for treating schizophrenia is 10 mg once daily. Therapy is initiated with 5-10 mg/day and the dose may be increased by 5 mg a day in weekly intervals. Doses greater than 10 mg daily have not been shown to be more effective than 10 mg daily. The safety and efficacy of doses greater than 20 mg daily have not been evaluated.

Treatment of bipolar disorder usually is initiated with oral doses of 10-15 mg once daily. The dose may be increased by 5 mg daily at 24 hour intervals. Doses greater than 20 mg daily have not been evaluated. In clinical trials, doses of 5-20 mg daily were effective.

The usual dose for treating agitation due to schizophrenia or bipolar disorder is 10 mg administered by intramuscular injection. Additional 10 mg doses may be administered, but the efficacy of total daily doses greater than 30 mg daily have not been adequately evaluated.

Olanzapine is eliminated from the body more quickly in young people than in older (over age 60) individuals, in men than in women, and in smokers faster than in non-smokers. Dosage adjustments may be needed based upon individual patient characteristics.

Information Associated with Product:

**SIDE EFFECTS****Olanzapine may cause side effects.**

- \* drowsiness
- \* dizziness
- \* restlessness
- \* unusual behavior
- \* depression
- \* difficulty falling asleep or staying asleep



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- \* weakness
- \* difficulty walking
- \* constipation
- \* weight gain
- \* dry mouth
- \* pain in arms, legs, back, or joints

**Some side effects can be serious.**

- \* seizures
- \* changes in vision
- \* swelling of the arms, hands, feet, ankles, or lower legs
- \* unusual movements of your face or body that you cannot control
- \* fever
- \* very stiff muscles
- \* excess sweating
- \* fast or irregular heartbeat
- \* rash
- \* hives
- \* difficulty breathing or swallowing



**PRECAUTIONS**

precaution should be used in patients with heart disease because the drug may cause blood pressure to fall too low resulting in dizziness, rapid heartbeats, or fainting. Olanzapine should be used carefully in people with known seizure disorders since olanzapine may alter properties of the brain making seizures occur more easily. People with liver disease should have their liver function monitored regularly while taking olanzapine. Women who are pregnant or breast-feeding should not take olanzapine. People with phenylketonuria, a disorder in which the body is unable to metabolize a protein called phenylalanine, should avoid olanzapine disintegrating tablets, because this form of the drug contains phenylalanine.

Before taking olanzapine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have a history of the following: neuroleptic malignant syndrome (see also Side Effects section). Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver problems, low blood pressure, breast cancer, stroke, dementia, Alzheimer's disease, seizures, prostate problems, glaucoma (narrow angle type), intestinal disease, difficulty swallowing, tardive dyskinesia (see also Side Effects section), smoking. (See also Side Effects section.) Also tell your doctor or pharmacist if either you or a family member has a history of the following: diabetes, heart disease, high blood cholesterol/triglyceride levels, high blood pressure, obesity. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages. This medication can make you prone to heat stroke. Avoid activities that might cause you to overheat (e.g., doing strenuous work, exercising in hot weather, or using hot tubs). Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially dizziness, drowsiness, or seizures. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

**INTERACTION**

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: carbamazepine, fluvoxamine, drugs for high blood pressure, omeprazole, drugs for Parkinson's disease, rifampin.



Report drugs that cause drowsiness such as medicine for sleep (e.g., sedatives), tranquilizers, anti-anxiety drugs (e.g., diazepam), narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., phenothiazines such as chlorpromazine, or tricyclics such as amitriptyline), anti-seizure drugs (e.g., phenytoin), muscle relaxants, antihistamines that cause drowsiness (e.g., diphenhydramine). Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about the safe use of those products. Do not start or stop any medicine without doctor or pharmacist approval.

## DRUG DESCRIPTION

Olanzapine is a typical antipsychotic for the treatment of: schizophrenic depressive episodes associated with bipolar disorder, as part of the Symbyax formulation acute manic episodes and maintenance treatment in bipolar disorder.

Olanzapine is a yellow crystalline solid, which is practically insoluble in water. Each tablet contains olanzapine equivalent to 2.5 mg (8 µmol), 5 mg (16 µmol), 7.5 mg (24 µmol), 10 mg (32 µmol), 15 mg (48 µmol), or 20 mg (64 µmol). Inactive ingredients are carnauba wax, crospovidone, hydroxypropyl cellulose, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, and other inactive ingredients.

Olanzapine is a medication that is used to treat schizophrenia and acute manic episodes associated with bipolar I disorder. Olanzapine belongs to a drug class known as atypical antipsychotics. Other members of this class include clozapine (Clozaril), risperidone (Risperdal), aripiprazole (Abilify) and ziprasidone (Geodon). The exact mechanism of action of olanzapine is not known. It may work by blocking receptors for several neurotransmitters (chemicals that nerves use to communicate with each other) in the brain. It binds to alpha-1, dopamine, histamine H-1, muscarinic, and serotonin type 2 (5-HT<sub>2</sub>) receptors.

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91 022 30601000.

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