- Hypersensitivity
- Diabetes or the worsening of diabetes, occasionally associated with ketoacidosis or coma
- Seizures
- Muscle stiffness or spasms
- Memory loss or forgetfulness
- Urinary incontinence, lack of ability to urinate.
- Hair loss.
- Absence or decrease in menstrual periods.
- Changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects :

- Lowering of normal body temperature
- Abnormal rhythms of the heart
- Prolonged and/or painful erection. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen on blood tests and an increase in a type of white blood cells (eosinophilia).

Presentation

Lanzapin 10mg is available in blister pack of 10 tablets.
Lanzapin 5mg is available in blister pack of 10 tablets.

Storage conditions and other information

- Keep this medicine out of sight and reach of children.
- Store below 25°C Store away from direct sunlight, heat, and moisture.

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

Art No. 554/1

Lanzapin 10 mg & 5 mg Tablets

(Olanzapine)

COMPOSITION

LANZAPIN 10MG TABLET

Each tablet contains:
Olanzapine (USP Specs) …… 10mg
Product complies USP Specs

LANZAPIN 5MG TABLET

Each tablet contains:
Olanzapine (USP Specs) …… 5mg
Product complies USP Specs

CLINICAL PHARMACOLOGY

Pharmacodynamics:

Olanzapine is an antipsychotic, antimanic and mood-stabilizing agent that demonstrates a broad pharmacologic profile across many receptor systems.
In preclinical studies, olanzapine exhibited a range of receptor affinities (Ki < 100 nM) for serotonin 5 HT2A/2C, 5 HT3, 5 HT6; dopamine D1, D2, D3, D4, D5; cholinergic muscarinic receptors M1-M5; α1 adrenergic; and histamine H1 receptors. Olanzapine demonstrated a greater in vitro affinity for serotonin 5HT2 than dopamine D2 receptors and greater 5 HT2 than D2 activity in vivo models. Electrophysiological studies demonstrated that olanzapine selectively reduced the firing of mesolimbic (A10) dopaminergic neurons while having little effect on the striatal (A9) pathways involved in motor function. Olanzapine reduced a conditioned avoidance response, a test indicative of antipsychotic activity, at doses below those producing catalepsy, an effect indicative of motor side-effects. Unlike some other antipsychotic agents, olanzapine increases responding in an "anxiolytic" test.
In a single oral dose (10 mg) Positron Emission Tomography (PET) study in healthy volunteers, olanzapine produced a higher 5 HT2A than dopamine D2 receptor occupancy. Besides, a Single Photon Emission Computed Tomography SPECT imaging study in schizophrenic patients revealed that olanzapine-responsive patients had lower striatal D2 occupancy than some other antipsychotic- and risperidone-responsive patients while being comparable to clozapine-responsive patients.

Pharmacokinetics:

Olanzapine is well absorbed after oral administration, reaching peak plasma concentrations within 5 to 8 hours. The absorption is not affected by food. Absolute oral bioavailability relative to intravenous administration has not been determined. The plasma protein binding of olanzapine was about 93 % over the concentration range of about 7 to 1000 ng/ml. Olanzapine is bound predominantly to albumin and α 1-acid-glycoprotein. Olanzapine is metabolized in the liver by conjugative and oxidative pathways. The major circulating metabolite is the 10-N-glucuronide, which does not pass the blood-brain barrier. Cytochromes P450- CYP1A2 and P450-CYP2D6 contribute to the formation of the N-desmethyl and 2-hydroxymethyl metabolites, both exhibited significantly less in vivo pharmacological activity than olanzapine in animal studies. The predominant pharmacologic activity is from the parent olanzapine. In healthy elderly (65 and over) versus non-elderly subjects, the mean elimination half-life was prolonged (51.8 versus 33.8 hr) and the clearance was reduced (17.5 versus 18.2 l/hr). In female versus male subjects the mean elimination half-life was somewhat prolonged (36.7 versus 32.3 hr) and the clearance was reduced (18.9 versus 27.3 l/hr). However, olanzapine (5-20 mg) demonstrated a comparable safety profile in female (n=467) as in male patients (n=869).
In renally impaired patients (creatinine clearance < 10 ml/min) versus healthy subjects, there was no significant difference in mean elimination half-life (37.7 versus 32.4 hr) or clearance (21.2 versus 25.0 l/hr). A mass balance study showed that approximately 57 % of radiolabelled olanzapine appeared in urine, principally as metabolites.

Effects of this medicine

Lanzapin tablet contain the active substance olanzapine. Olanzapine belongs to a group of medicines called antipsychotics and is used to treat the following conditions:

• Schizophrenia a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.

• Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.Olanzapine has been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

Before using this medicine, be sure to tell your doctor and pharmacist

Do not take Olanzapine

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine.
- If you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye)
- The use of Olanzapine in elderly patients with dementia is not recommended as it may have serious side effects.
- Medicines of this type may cause unusual movements mainly of the face or tongue.
- Weight gain has been seen in patients taking Olanzapine.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking Olanzapine. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Olanzapine and regularly during treatment.
- Tell the doctor if you or someone else in your family has a history of blood clots, as medicines like these have been associated with the formation of blood clots.
- As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor. Olanzapine is not for patients who are under 18 years.
- Do not drink any alcohol if you have been given Olanzapine as together with alcohol it may make you feel drowsy.
- If you are pregnant or breast-feeding you should not be given this medicine as small amounts of Olanzapine can pass into breast milk. The following symptoms may occur in newborn babies, of mothers that have used olanzapine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.
- There is a risk of feeling drowsy when you are given Olanzapine. If this happens do not drive or operate any tools or machines.
- Olanzapine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Dosing schedule (How to take this medicine?)

Schizophrenia: The recommended starting dose for olanzapine is 10 mg/day.

Manic episode: The starting dose is 15 mg as a single daily dose in monotherapy or 10 mg daily in combination therapy Preventing recurrence in bipolar disorder: The recommended starting dose is 10 mg/day. For patients who have been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose. During treatment for schizophrenia, manic episode and recurrence prevention in bipolar disorder, daily dosage may subsequently be adjusted on the basis of individual clinical status within the range 5- 20 mg/day. An increase to a dose greater than the recommended starting dose is advised only after appropriate clinical reassessment and should generally occur at intervals of not less than 24 hours. Olanzapine can be given without regards for meals as absorption is not affected by food. Gradual tapering of the dose should be considered while discontinuing olanzapine.

You should take our Olanzapine tablet once a day following the advice of your doctor. Try to take your tablets at the same time each day. It does not matter whether you take them with or without food. Olanzapine tablets are for oral use. You should swallow the Olanzapine tablets whole with water.

If you take more Olanzapine than you should

• Patients who have taken more Olanzapine than they should, have experienced the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness.

• Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart. Contact your doctor or hospital straight away if you experience any of the above symptoms. Show the doctor your pack of tablets. If you forget to take Olanzapine take your tablet as soon as you remember. Do not take two doses in one day.

If you stop taking Olanzapine

• Do not stop taking your tablet just because you feel better. It is important that you carry on taking Olanzapine for as long as your doctor tells you. If you suddenly stop taking Olanzapine, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Precautions while taking this medicine

Talk to your doctor or pharmacist before you take Olanzapine.

- The use of Olanzapine in elderly patients with dementia is not recommended as it may have serious side effects.
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olanzapine tell your doctor.
- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor once.
- Weight gain has been seen in patients taking Olanzapine. You and your doctor should check your weight regularly.
- Consider referral to a dietitian or help with a diet plan if necessary.
- If you suffer from any of the following illnesses tell your doctor as soon as possible:
- Diabetes
- Heart disease
- Liver or kidney disease
- Parkinson's disease
- Seizures
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Blood disorders
- Stroke or "mini" stroke (temporary symptoms of stroke)

Possible adverse reactions to this medicine

- unusual movement mainly of the face or tongue
- blood clots in the veins especially in the legs
- weight gain; sleepiness; and increase in levels of prolactin in the blood. In the early stages of treatment, some people may feel dizzy or faint , especially while getting up from a lying or sitting position.

Common side effects:

• changes in the count of some blood cells, circulating fats and early in treatment, temporary increases in liver enzymes.

- increase in the level of sugars in the blood and urine.
- increase in levels of uric acid and creatine phosphokinase in the blood
- feeling more hungry.
- joint pain and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects: