

TOLANZ TABLET

Olanzapine (5 mg, 10 mg)

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What Tolanz is used for

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such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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.
- Maintaining the clinical improvement during continuation therapy in people who have shown an initial treatment response.
- Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

Tolanz has been shown to prevent recurrence of these symptoms in individual with bipolar disorder whose manic episode has responded to Tolanz treatment.

How Tolanz works

Olanzapine acts on a receptors named as serotonin receptors and by this it exhibits antipsychotic properties.

Before you use Tolanz

- When you must not use it

Do not take Tolanz:

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of Tolanz. An allergic reaction may be recognized as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.
- If you have been previously diagnosed with eye problems such

as certain kinds of glaucoma (increased pressure in the eye).

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You should not be given this medicine when breast-feeding, as small amounts of Tolanz can pass into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

The following symptoms may occur in newborn babies, of mothers that have used Tolanz in the last trimester (last three months of their pregnancy):

- Shaking.
- Muscle stiffness and/or weakness.
- Sleepiness.
- Agitation.
- Breathing problems.
- Difficulty in feeding.

If your baby develops any of these symptoms you may need to contact your doctor.

- Before you start use it

Talk to your doctor or pharmacist before you take Tolanz:

- During antipsychotic treatment, improvement in the individual's clinical condition may take several days to some weeks. They should be closely monitored during this period.
- The use of Tolanz 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 Tolanz 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 at once and the medicine must be discontinued.
- Weight gain has been seen in individual taking Tolanz. You and your doctor should check your weight regularly.

- If combination of three or more of the following is seen, please discontinue the medicine:

- Redness and peeling of the skin over large areas of the body.
- An increase in the number of eosinophils in the blood.
- Fever.
- Abnormality in size, number, or consistency of lymphnodes.
- Inflammation of liver.
- Inflammation of kidneys.
- Inflammation of the walls of the air sacs in the lungs.
- Inflammation of cardiac muscles.

- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in individual taking Tolanz. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Tolanz and regularly during treatment.
- If high blood sugar levels are observed and Tolanz needs to be discontinued, improvement in your clinical condition may take several days to some weeks after discontinuation of Tolanz. Close monitored during this period is required.
- 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.

If you suffer from any of the following illnesses tell your doctor as soon as possible:

- Stroke or "mini" stroke (temporary symptoms of stroke).
- Parkinson's disease.
- Prostate problems.
- A blocked intestine (Paralytic ileus).
- Liver or kidney disease.
- Blood disorders.
- Heart disease.
- Diabetes.
- Seizures.
- Low white blood cells and/or neutrophil (a type of white blood cell) counts.

If you suffer from dementia, you or your carer/relative should tell you

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doctor if you have ever had a stroke or “mini” stroke.

As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

Children and adolescents

Tolanz is not for individual who are under 18 years.

Talk to your doctor or pharmacist if you:

- Have or are at risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking Tolanz and regularly during treatment.

- Taking other medicines

Only take other medicines while you are on Tolanz if your doctor tells you that you can. You might feel drowsy if Tolanz is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking:

- Medicines for Parkinson’s disease.
- Carbamazepine (an anti-epileptic and mood stabilizer).
- Fluvoxamine (an antidepressant).
- Ciprofloxacin (an antibiotic).
- Ketoconazole (an antifungal).
- Activated charcoal.

How to use Tolanz

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should take your Tolanz tablets once a day following the advice of your doctor. The daily dose of Tolanz is between 5mg and 20 mg.

Your doctor will tell you how long you should continue to take your tablet. Consult your doctor if your symptoms return but do not stop taking Tolanz unless your doctor tells you to.

- When to use it

Try to take your tablets at the same time each day.

- How long to use it

Do not stop taking your tablets just because you feel better. It is important that you carry on taking Tolanz for as long as your doctor tells you.

If you suddenly stop taking Tolanz, 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 forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

People who have taken more Tolanz 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, 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

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- You can take Tolanz with or without food. You should swallow the Tolanz tablets whole with water.

- Tell all the doctors, dentists and pharmacists treating you that you are taking Tolanz.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Tolanz to anyone else, even if they have the same symptoms or condition as you.
- Do not drink any alcohol if you have been given Tolanz as together with alcohol it may make you feel drowsy.

- Things to be careful of

Driving and using machines

There is a risk of feeling drowsy when you are given Tolanz. If this happens do not drive or operate any tools or machines and contact your doctor immediately.

Side effects

Like all medicines, Tolanz can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have:

- Unusual movement mainly of the face or tongue.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Very common side effects include:

- Weight gain.
- Sleepiness.
- Increases in levels of prolactin in the blood.

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- Feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position.

Common side effects include:

- Changes in the levels of some blood cells and circulating fats.
- Temporary increases in liver enzymes.
- Increases in the level of sugars in the blood and urine.
- Increases in levels of uric acid and creatine phosphokinase (is an enzyme that helps to elicit chemical changes in your body) in the blood.
- Feeling more hungry.
- Dizziness.
- Restlessness.
- Tremor.
- Unusual muscle movements (dyskinesia).
- Constipation.
- Dry mouth.
- Rash.
- Loss of strength.
- Extreme tiredness.
- Water retention leading to swelling of the hands, ankles or feet.
- Fever.
- Joint pain.
- Sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

While taking Tolanz, elderly individual with dementia may suffer from:

- Stroke.
- Pneumonia (infection of the lungs that is caused by bacteria, viruses, fungi, or parasites).
- Urinary incontinence.
- Falls.
- Extreme tiredness.
- Visual hallucinations.
- Have trouble walking.

Some fatal cases have been reported in this particular group of elderly people.

In individual with Parkinson's disease Tolanz may worsen the symptoms.

Talk to your doctor or pharmacist if you experience:

- Increase in blood sugar level and / or symptoms of high blood sugar (e.g. increased thirst, increased hunger and frequent urination).

- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome).
- Trouble breathing during sleep (sleep apnoea).
- Difficulty or inability to pass urine (urinary retention).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Tolanz

- Storage

- Keep out of reach of children.
- Store below 30°C, Protected from light and moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

TOLANZ TABLET 5 MG:
Yellow colored, round, biconvex uncoated tablets debossed with “5” on one side and “67” on other side.

TOLANZ TABLET 10 MG:
Yellow colored, round, biconvex uncoated tablets debossed with “10” on one side and “169” on other side.

Ingredients

Active ingredient:

- Olanzapine.

Inactive ingredients:

- Mannitol.
- Crospovidone.
- Cellulose, microcrystalline.
- Magnesium stearate.

- MAL number(s):

TOLANZ TABLET 5 MG:
MAL19041002AZ

TOLANZ TABLET 10 MG:
MAL19041003AZ

Manufacturer

Torrent Pharmaceuticals LTD.
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Product Registration Holder

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