PACKAGE LEAFLET: Information for the patient

OLANZAPIN

Film-coated tablets – 10 mg

(Olanzapine)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

In this leaflet:

1. WHAT OLANZAPIN IS AND WHAT IT IS USED FOR

Olanzapine belongs to a group of medicines called antipsychotics.

Olanzapin is used for the treatment of schizophrenia and moderate to severe manic episode, which is associated with bipolar disorders.

This drug treats symptoms such as: hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness. People with this disease may also feel depressed, anxious or tense.

Also, Olanzapin is used to treat symptoms such as feeling "high", having excessive amounts of energy and sometimes severe irritability. It is also a mood stabilizer.

2. BEFORE YOU TAKE OLANZAPIN

Do not take Olanzapin if:

- you are allergic (hypersensitive) to olanzapine or to any of the excipients of the tablet; an allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath; if this has happened to you, tell your doctor;
- you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).

Take special care with Olanzapin

Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Olanzapin, 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.

The use of Olanzapin in elderly patients with dementia is not recommended as it may cause serious side effects.

Weight gain has been seen in patients taking olanzapine. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.

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 Olanzapin 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.

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;
- epilepsy;
- prostate problems;
- a blocked intestine (paralytic ileus);

- blood disorders;
- stroke or "mini" stroke (temporary symptoms of stroke);
- you may have salt depletion as a result of prolonged severe diarrhoea and vomiting or usage of diuretics (water tablets).

If you suffer from dementia, you or your carer / relative should tell your doctor if you have ever had a stroke or "mini" stroke.

If you are over 65 years your blood pressure may be monitored by your doctor.

Olanzapin is not for patients who are under 18 years old.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You may take other medicines while you are on Olanzapin only if your doctor tells you that you can.

You might feel drowsy if you take Olanzapin concomitantly with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

You should tell your doctor if you are taking carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant) or ciprofloxacin (an antibiotic), as it may be necessary to change your Olanzapin dose.

Especially tell your doctor if you are taking medicines for Parkinson’s disease.

Taking Olanzapin with food and drinks

The tablets may be taken with or without food.

Do not drink any alcohol if you have been given Olanzapin as Olanzapin and alcohol together may make you feel drowsy.

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or planning to have a baby.

The following symptoms may occur in newborn babies of mothers that have used olanzapine tablets 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.
You should not breastfeed while you are taking this medicine, as small amounts of olanzapine can pass into breast milk.

Driving and using machines

You should not drive or use machines if you are given Olanzapin because this medicine may cause drowsiness.

Important information about some of the excipients of Olanzapin

Olanzapin 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.
The film coating used in Olanzapin tablets contains an azo colouring agent, Allura red AC (E 129), which may cause allergic reactions.

3. HOW TO TAKE OLANZAPIN

Always take Olanzapin exactly as your doctor has told you.
Your doctor will tell you the dose of Olanzapin you should take and for how long.
The daily dose of Olanzapine is between 5 and 20 mg.
Consult your doctor if your symptoms return but do not stop the treatment unless your doctor tells you to.
Olanzapin is taken once a day. Try to take your tablets at the same time each day.
Olanzapin film-coated tablets should be swallowed whole with water.

If you take more Olanzapin than you should

If you take more Olanzapin than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.
The overdose symptoms include: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness, acute confusion, seizures (epilepsy), coma, a combination of some symptoms (fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness), slowing of the

breathing rate, high blood pressure or low blood pressure, abnormal rhythms of the heart.

If you forget to take Olanzapin

If you forget to take Olanzapin, take the tablet as soon as possible. Do not take two doses in one day.

If you stop taking Olanzapin

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

If you suddenly stop taking Olanzapin, symptoms such as sweating, unability to sleep, tremor, anxiety or nausea and vomiting might occur.

Your doctor may suggest you to reduce the dose gradually before stopping treatment.

4. POSSIBLE SIDE EFFECTS

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

The majority of side effects are dose-related and disappear when the dose is reduced or the treatment discontinued. Some side effects can occur at the beginning of treatment and resolve spontaneously as the treatment continues.

The frequency of possible side effects is shown in the table below:

Very common:	occur in more than 1 in 10 users
Common:	occur in less than 1 in 10, but more than 1 in 100 users
Uncommon:	occur in less than 1 in 100 users but more than 1 in 1,000 users
Rare:	occur in less than 1 in 1,000, but more than 1 in 10,000 users
Very rare:	occur in less than 1 in 10.000 users, including isolated cases

Tell your doctor immediately if you have:

- unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue;
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) 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;

- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (the frequency of this side effect cannot be estimated from the available data).

Very common side effects:

- weight gain;
- sleepiness;
- increases in the levels of prolactin in the blood.

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. If this effect does not pass on its own, tell your doctor.

Common side effects:

- changes in the levels of some blood cells, circulating fats and early in treatment, 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 in the blood;
- feeling more hungry;
- dizziness;
- restlessness;
- tremor;
- unusual movements (especially of the face or tongue);
- 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.

Uncommon side effects include hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms (including eye movements); restless legs syndrome; problems with speech; slow heart rate; sensitivity to sunlight; bleeding from nose; abdominal distension; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease in menstrual periods; and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Very rare side effects include serious allergic reactions such as 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 in blood tests and an increase in a type of white blood cell (eosinophilia).

Other possible side effects:

- lowering of normal body temperature;
- abnormal rhythms of the heart;
- sudden unexplained death;
- inflammation of the pancreas causing severe stomach pain, fever and vomiting;
- liver disease appearing as yellowing of the skin and white parts of the eyes;
- muscle disease presenting as unexplained aches and pains.

While taking Olanzapin, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and may have trouble walking. Some fatal cases have been reported in this particular group of patients.
In patients with Parkinson's disease Olanzapin may worsen the symptoms.
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.

5. HOW TO STORE OLANZAPIN

Keep out of the reach and sight of children!

Do not use Olanzapin after the expiry date, which is stated on the package.

Do not store above 25 °C!

Store in the original package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose them.

6. FURTHER INFORMATION

What Olanzapin –film-coated tablet 10 mg contains

The **active substance** is olanzapine.

One film-coated tablet contains 10 mg olanzapine.

The **excipients** are:

tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone, hydroxypropyl cellulose, magnesium stearate.

film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, indigo carmine, Allura red AC (colouring agent), black iron oxide.

Contents of the pack

Box with 30 film-coated tablets.

Marketing authorisation holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in September 2023.