This medicine is to be supplied by a doctor's prescription only

Zyprexa	Zyprexa	Zyprexa
5 mg	7.5 mg	10 mg
Tablets	Tablets	Tablets
Composition:	**Composition:**	**Composition:**
Each tablet contains:	Each tablet contains:	Each tablet contains:
Olanzapine 5 mg	Olanzapine 7.5 mg	Olanzapine 10 mg

For the list of inactive ingredients, please see section 6.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

Very important information about this medicine:
Antipsychotics (like **Zyprexa**) can increase the risk of death in elderly people who are experiencing confusion, memory loss, and loss of touch with reality (dementia associated with psychosis). This medicine is not intended for adult patients who suffer from psychosis related to dementia.

Zyprexa is intended for adults over 18 years of age, due to the lack of information about its efficacy and safety in children and adolescents under 18 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Zyprexa is an antipsychotic agent for the treatment of schizophrenic patients and symptoms of psychotic disorders.

In addition, it is intended for the treatment of bipolar affective disorder.

Therapeutic group:

Atypical antipsychotic medicines.

2. BEFORE USING THIS MEDICINE:

Do not use this medicine if:

- You are sensitive to Olanzapine or to any of the other ingredients that this medicine contains. Signs of an allergic reaction include: rash, difficulties swallowing or breathing, swelling of the lips, face, throat or tongue.
- You are at risk of eye problems such as narrow-angle glaucoma (increased pressure in the eye).

Special warnings regarding the use of this medicine:

- Avoid situations in which excessive increase in body temperature and dehydration are possible, such as increased physical activity or frequent stay in hot places. Be sure to drink fluids to prevent dehydration.
- **Zyprexa** may cause hypotension upon transition from a lying to sitting position. The symptoms include: dizziness, slow or rapid heart rate, and even fainting in some patients. This side effect usually occurs at the beginning of treatment.
- **Zyprexa can cause drowsiness, drop in blood pressure when changing position from lying down to sitting up, and motoric and sensory instability; these can cause falls and may result in fractures and other injuries.** Use with caution and consider the risks against the benefits in patients with underlying conditions or who are taking medicines that may increase the risk of falls.
- Weight gain has been observed in patients taking **Zyprexa**. Weight should be monitored regularly.
- The blood levels of glucose and lipids should be monitored since **Zyprexa** may cause an increase in these parameters.

- In patients with a medical history of low levels of white blood cells, blood count tests should be regularly performed during the first months of treatment for follow up. **Zyprexa** may cause a decrease in the levels of white blood cells. Discontinuation of **Zyprexa** treatment should be considered upon appearance of the first symptom of this condition. Patients with reduced levels of white blood cells must be monitored for symptoms indicating infection or fever. If any of these are experienced, immediately discontinue the treatment with **Zyprexa.**
- Taking **Zyprexa** is not recommended for elderly patients suffering from dementia due to the probability of severe side effects: falls, drowsiness, peripheral oedema, abnormal walking, urinary incontinence, extreme tiredness, weight gain, weakness, fever, pneumonia, dry mouth, visual hallucinations, stroke and death.
- Patients with schizophrenia and bipolar disorders are at a greater risk of attempted suicide. Therefore, these patients must be closely monitored while being treated with **Zyprexa**.

Before treatment with Zyprexa tell your doctor if:

- You suffer or have previously suffered from cardiac dysfunction.
- You suffer or have previously suffered from a stroke or "mini" stroke (temporary symptoms of stroke).
- You suffer from problems with the liver, gastrointestinal system (such as bowel obstruction).
- You suffer from problems in the blood system, nervous system, Alzheimer's disease, bone marrow, breast cancer.
- You experience suicidal thoughts.
- You suffer or have previously suffered from enlargement of the prostate gland.
- You suffer from epilepsy, diabetes or high blood glucose levels, high or low blood pressure, high blood levels of cholesterol or triglycerides.
- You are sensitive to a certain type of food or medicine.
- You are sensitive to lactose - **Zyprexa** contains lactose and may cause sensitivity in people sensitive to lactose.

If you are taking other medicines, including nonprescription medications and food supplements, inform your doctor or pharmacist. In particular, you must inform the doctor or pharmacist if you are taking:

- Diazepam: Co-administration of **Zyprexa** and diazepam may cause hypotension upon transition from a lying to sitting position (orthostatic hypotension).

- Medicines affecting the CYP1A2 enzyme, e.g.: carbamazepine, fluvoxamine, omeprazole and rifampicin – may affect the levels of olanzapine in the blood.
- Medicines containing activated charcoal – may reduce the absorption of olanzapine.
- Medicines affecting the central nervous system such as sedatives, antidepressants and sleep medications, anti-epileptic medicines – care should be taken upon concomitant administration of these medicines and olanzapine.
- Medicines used to reduce high blood pressure – olanzapine may enhance the blood pressure lowering effect upon concomitant administration with these medicines.
- Medicines that mimic the action of dopamine (such as Levodopa, a drug for the treatment of Parkinson's disease) - olanzapine may inhibit the activity of these medicines.

Taking Zyprexa with food and drinks:
Zyprexa may be taken with or without food.

Use of this medicine and alcohol consumption:
Avoid alcohol consumption while using **Zyprexa**.

Pregnancy and breastfeeding:
Consult a doctor or pharmacist before taking this medicine.
Consult a doctor if you are pregnant or planning to get pregnant. Neonates may develop a withdrawal syndrome if the mother has taken the medicine during the last trimester (the last 3 months) of pregnancy. The withdrawal syndrome includes the following symptoms: restlessness, tremor, muscle stiffness/weakness, drowsiness, irritability, respiratory and feeding problems. If your child develops one or more of the above symptoms, contact the doctor.

Do not use this medication if you are breastfeeding.

Driving and using machines:
Use of this medicine may affect the judgment capability, thinking capability and motor skills, therefore caution should be exercised while driving a car, operating dangerous machines and performing any activity requiring alertness.

Smoking:

If you are smoking – inform your doctor prior to beginning treatment with this medicine.

3. HOW TO USE THIS MEDICINE?

- Always use according to the doctor's instructions. You must check with the doctor or pharmacist if you are not sure.
- The dosage and manner of treatment will be determined only by the doctor.
- **Do not exceed the recommended dose.**
- There is no information about crushing or splitting this medicine, so do not chew, crush or split the tablets! Swallow the medicine with some water.
- There is no information about using this medicine with a nasogastric tube.
- Use this medicine at regular time intervals as determined by your doctor.
- **If you have accidentally taken a higher dose** you may feel drowsy, experience impaired speech, aggressiveness or restlessness, rapid heart rate and reduced levels of consciousness.

  If you have taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a hospital Emergency Room and bring the medicine package with you.
- If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.
- Persist with the treatment as recommended by the doctor.
- Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor or pharmacist.
- **If you stop taking the medicine** you may experience: nausea, vomiting and sweating.
- Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

Tests and follow-up:

- At the beginning and during treatment, blood glucose levels should be monitored, especially if you have diabetes or borderline glucose levels (fasting levels of 100-126 mg/dL); blood lipid levels should also be monitored, especially in patients with impaired blood lipid levels or risk factors of developing such disorders.
- Gaining weight is a common side effect of treatment with **Zyprexa**. This should be taken into account prior to beginning the treatment and weight should be routinely monitored.

- In patients with a history of low white blood cell levels, white blood cell levels should be monitored during the first months of treatment. Discontinuation of treatment with Zyprexa should be considered upon appearance of the first significant symptom indicating reduced white blood cell levels.

  If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, **Zyprexa** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Zyprexa may cause serious side effects:

1. **Increased risk of death** in elderly patients who are experiencing confusion, memory loss, and loss of touch with reality (psychosis associated with dementia). **Zyprexa** is not intended for use in elderly patients with dementia.
2. **Increase in blood glucose levels (hyperglycemia)** may occur in patients who are diabetic and in patients who are not diabetic. Increase in blood glucose levels may cause:
    - ketoacidosis - increased level of acid in the blood due to build-up of ketones
    - coma
    - death

    Your doctor must order blood tests to regularly monitor your blood glucose levels before and during treatment with **Zyprexa**. Patients who are not diabetic may experience an increase in blood glucose levels when they stop taking **Zyprexa**. Patients who are diabetic and some patients, who were not diabetic when they started **Zyprexa,** may need a medicine to reduce their blood glucose when they stop taking **Zyprexa**.

    If you have diabetes, your doctor will tell you how often to have blood tests for blood glucose levels.

    Consult a doctor if you experience symptoms of high blood glucose levels:
    - increased thirst
    - frequent urination
    - increased appetite
    - feeling tired and weak
    - nausea
    - confusion or fruity breath odor
3. **Increase in blood fat and cholesterol levels** may occur in patients who are being treated with **Zyprexa**. Your doctor must order blood tests for blood cholesterol and fat levels before you start treatment and while you are taking it even if you are not experiencing any symptoms.
4. **Weight gain** is very common in patients who are taking **Zyprexa**. Some patients experience extreme weight gain, so your doctor must weigh you during the course of treatment with **Zyprexa**. Consult your doctor about watching your weight by healthy eating and physical exercise.

5. **Increased frequency of stroke or "mini" stroke, transient ischemic attack (TIA) in elderly people with psychosis associated with dementia (elderly people who are experiencing loss of touch with reality due to confusion and memory loss). Zyprexa is not approved for use in these patients.**
6. **Neuroleptic malignant syndrome** - a rare but serious condition which may occur in patients who are taking antipsychotic medicines, including **Zyprexa**. Neuroleptic malignant syndrome may cause death and requires hospitalization. Refer to the doctor immediately if you experience:
    - high fever
    - increased sweating
    - stiff muscles
    - confusion
    - changes in your breathing, heart rate, and blood pressure
7. **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).** This side effect may include: rash, fever, swollen glands and implication of other internal organs such as: liver, kidneys, lungs and heart. This side effect can be lethal in some cases, so tell your doctor immediately if you experience any of these signs.
8. **Tardive dyskinesia** is a condition that causes involuntary movements, mainly of the face or tongue. This side effect may continue even after you stop taking **Zyprexa**. This side effect may start also after you stop taking **Zyprexa**. Tell your doctor if you are having involuntary body movements.
9. **Drop in blood pressure when changing position** including symptoms such as dizziness, fast or slow heart rate, or fainting.
10. **Difficulty swallowing** which may cause food or beverages to penetrate into your lungs.
11. **Seizures** - tell your doctor if you experience seizures while using **Zyprexa**.
12. **Problems regulating body temperature** - you may experience an increase in body temperature, for example when you exercise or when you are in a very hot place. It is important to drink water to prevent dehydration. See your doctor immediately if you become very ill and have symptoms of dehydration:
    - excessive sweating or lack of sweat
    - dry mouth
    - fever
    - increased thirst, urine retention

Additional side effects:

Very common side effects:
Weakness, dry mouth, constipation, indigestion, drowsiness, dizziness, injury from an accident, sleep disorders, parkinsonism.

Common side effects:
Fever, tremors, back ache, chest pain, pain in your limbs, joint pain, increased heart rate, high blood pressure, vomiting, physical restlessness, increased appetite, behavioral changes, increased triglyceride levels in the blood, weight gain, drop in blood pressure when changing position from lying down to sitting up, bleeding under the skin that is visible as patches on the skin, peripheral edema, abnormal gait, stiff muscles, speech impediment, runny nose, cough, lazy eye, inflammation of the esophagus, sleepiness, urinary incontinence, urinary tract infection, increased prolactin levels, increased blood levels of alkaline phosphatase, discharge of milk from the breasts, enlarged breasts in men.

Uncommon side effects:
Chills, facial edema, sensitivity to sunlight, attempted suicide, stroke, vasodilatation, nausea, vomiting, tongue edema, reduced white blood cell levels, reduced blood platelet levels, high blood levels of bilirubin, low blood levels of proteins, coordination problems, impaired speech, reduced libido, lack of sensitivity, nose bleeding, hair loss, dry eyes, changes in visual accommodation, impotence, changes in the menstrual cycle, urine retention, urinary frequency and urgency, large urine volume, breast pain, dystonia (spasm of the neck muscles, difficulties swallowing, difficulties breathing, tongue protrusion), abdominal distension and death due to diabetes.

Rare side effects:
Chills, fever, hangover effect, blocked intestine, fatty liver, osteoporosis, coma, pulmonary edema, dilated pupils, sudden death.

Side effects of unknown frequency:
Allergic reaction [such as: anaphylactic reaction, swelling of the face or throat (angioedema), itch, rash], diabetes-related coma, ketoacidosis, jaundice, pancreatitis and hepatitis, liver injury,

restless legs syndrome, neutropenia (reduced number of a certain type of white blood cells), painful and prolonged erection (priapism), painful muscle injury (rhabdomyolysis), venous thrombosis, stuttering.

If you experience any side effect, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" that can be found on the Home Page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW TO STORE THIS MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at room temperature, below 30^0C.

6. ADDITIONAL INFORMATION:

- In addition to the active ingredient, **Zyprexa** tablets also contain:
  Carnauba wax, crospovidone, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, edible blue ink.
  Zyprexa 5 mg tablets: contain 156 mg lactose/tablet.
  Zyprexa 7.5 mg tablets: contain 234 mg lactose/tablet.
  Zyprexa 10 mg tablets: contain 312 mg lactose/tablet.

- **What does the medicine look like and what are the contents of the package:**
  Zyprexa 5 mg tablets: packs of 28 white tablets with the text "LILLY" and the code "4115" imprinted on them.
  Zyprexa 7.5 mg tablets: packs of 28 white tablets with the text "LILLY" and the code "4116" imprinted on them.
  Zyprexa 10 mg tablets: packs of 28 white tablets with the text "LILLY" and the code "4117" imprinted on them.

- **License holder:** Eli Lilly Israel Ltd., P.O. Box 2160, Herzeliya Pituach 46120.

- **Manufacturer:** Lilly S.A., Alcobendas (Madrid), Spain.

- This leaflet was checked and approved by the Ministry of Health in June 2017, and was updated according to the Ministry of Health guidelines in March 2018.

- **Registration numbers in the National Drug Registry of the Ministry of Health:**
  Zyprexa 5 mg: 104-84-28857-00/21
  Zyprexa 7.5 mg: 104-85-28858-00/21
  Zyprexa 10 mg: 104-86-28859-00/21

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