

**Patient leaflet in accordance with the Pharmacists’
Regulations (Preparations) - 1986**

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

Zyprexa Velotab
5 mg

Orodispersible tablets

Active ingredient:

Each orodispersible tablet contains:
Olanzapine 5 mg

Zyprexa Velotab
10 mg

Orodispersible tablets

Active ingredient:

Each orodispersible tablet contains:
Olanzapine 10 mg

Inactive ingredients and allergens in this preparation: See section 6 “Additional information” and “Important information regarding some of the ingredients of this medicine” in section 2.

Read the entire leaflet carefully before you use 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.

Warning: Increased mortality in elderly patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. The increased risk of mortality could be observed whether these patients were treated with typical or atypical antipsychotics. **Zyprexa Velotab** can cause a serious side effect, including an increase in the risk of death in elderly people who are experiencing confusion, memory loss, and loss of touch with reality (dementia-related psychosis). **Zyprexa Velotab** is not approved for the treatment of elderly patients who suffer from dementia-related psychosis.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Acute and maintenance treatment of schizophrenia.

Zyprexa Velotab is indicated for the management of the manifestations of psychotic disorders.

Zyprexa Velotab is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

Prevention of recurrence in Bipolar Disorder:

In patients whose manic episode has responded to olanzapine treatment, **Zyprexa Velotab** is indicated for the prevention of recurrence in patients with Bipolar Disorder.

Combination therapy in Bipolar I Disorder:

The combination of **Zyprexa Velotab** with lithium or valproate is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

Therapeutic group:

Atypical antipsychotic medicines.

The symptoms of schizophrenia include hearing voices, seeing things that do not exist, believing in things that are not true, suspicion and disconnection.

The symptoms of bipolar I disorder include intermittent periods of depression and euphoria or nervousness, increased activity and restlessness, racing thoughts, rapid speech, impulsive behavior, and decreased need for sleep.

2. BEFORE USING THIS MEDICINE:**Do not use this medicine if:**

- You are sensitive (allergic) to olanzapine or to any of the other ingredients that this medicine contains.
For specific information on the contraindications of lithium or valproate, refer to the Contraindications section of the package inserts included in the packs of those products.

Special warnings regarding the use of this medicine

- **Zyprexa Velotab** interferes with the body's ability to reduce temperature. Situations in which there may be an increase in body temperature and dehydration, such as increased physical activity or frequent stays in hot places, should be avoided. Be sure to drink fluids to prevent dehydration.
- **Zyprexa Velotab** may cause low blood pressure 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 Velotab can cause drowsiness, low blood pressure upon transition from a lying to sitting position, and motor and sensory instability that can lead to falls resulting 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 Velotab**. Weight should be monitored regularly.
- Blood sugar and lipid levels should be monitored since **Zyprexa Velotab** 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 Velotab** may cause a decrease in the levels of white blood cells. Discontinuation of **Zyprexa Velotab** 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 fever or symptoms indicating infection. If any of these are experienced, immediately discontinue the treatment with **Zyprexa Velotab**.
- **Zyprexa Velotab** is not approved for the treatment of elderly patients suffering from dementia due to the probability of severe side effects: falls, drowsiness, peripheral

edema, abnormal walking, urinary incontinence, lethargy, weight gain, weakness, fever, pneumonia, dry mouth, visual hallucinations, stroke, and death.

- Patients with schizophrenia and bipolar disorder are at a greater risk of attempted suicide. Therefore, these patients must be closely monitored while being treated with **Zyprexa Velotab**.
- Caution should be exercised in patients who have suffered or are currently suffering from urinary retention, prostate enlargement, constipation or a history of intestinal obstruction, as the use of **Zyprexa Velotab** in these patients may cause symptoms such as constipation, dry mouth, and tachycardia. From experience gained after marketing the drug, it was found that the risk of serious side effects (including deaths) increased when combining **Zyprexa Velotab** with anticholinergic drugs.
- **Neuroleptic Malignant Syndrome** – This is a rare but very severe condition that could occur in patients taking antipsychotics, including **Zyprexa Velotab**. Symptoms include high fever, increased sweating, muscle stiffness, confusion, and changes in your breathing, heart rate, and blood pressure.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)**. This side effect may occur with **Zyprexa Velotab**. This side effect may include rash, fever, swollen glands, and the involvement of other internal organs such as the liver, kidneys, lungs, and heart.
- Tardive dyskinesia - **a condition that causes involuntary movements in the body which you can't control. The movements are usually of the face and tongue.** Such a condition may occur in patients taking antipsychotics, including **Zyprexa Velotab**.
- **Difficulty swallowing**, which may cause food or drink to get into your lungs, may occur in patients taking antipsychotics, including **Zyprexa Velotab**.
- **Seizures** – tell the doctor if you experience a seizure while using **Zyprexa Velotab**.
- **Zyprexa Velotab** causes **elevated prolactin levels**, which can lead to reversible harm to fertility in women of childbearing age and in men.

Before treatment with Zyprexa Velotab, tell the doctor if you suffer or have previously suffered from:

- cardiac problems
- a stroke or “mini stroke” (transient ischemic attack)
- seizures
- diabetes or high blood glucose levels (hyperglycemia)
- high or low blood pressure
- high blood levels of cholesterol or triglycerides
- Liver problems
- bowel obstruction
- Alzheimer’s disease
- breast cancer
- narrow-angle glaucoma
- thoughts of suicide or self-harm
- enlargement of the prostate gland (in men)
- any other medical condition.

Tell the doctor if you exercise a lot or stay in hot places often.

The symptoms of bipolar disorder or schizophrenia may include **suicidal thoughts** or thoughts of harming yourself or others. In this case, you should contact a doctor or Emergency Room immediately.

Smoking

If you smoke - inform the doctor prior to beginning treatment with this medicine.

Children and adolescents

Zyprexa Velotab is intended for adults over the age of 18.

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).
- You should monitor the levels of lipids (cholesterol and triglycerides) in the blood, especially in patients with disordered blood lipid levels or risk factors of developing such disorders. Blood tests for blood lipids should be performed at the beginning and during treatment, even if you do not have any symptoms.
- Weight gain is a common side effect of treatment with **Zyprexa Velotab**. 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 Velotab** should be considered upon appearance of the first significant symptom indicating reduced white blood cell levels.

Drug interactions

If you are taking or have recently taken other medicines, including over-the-counter medications and food supplements, inform the doctor or pharmacist.

Especially if you are taking:

- Diazepam: co-administration of **Zyprexa Velotab** and diazepam may cause low blood pressure upon transition from a lying to sitting position (orthostatic hypotension).
- Medicines affecting the CYP1A2 enzyme, such as 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 lower 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 and agonists for dopamine) - olanzapine may inhibit the activity of these medicines.
- Anticholinergic drugs - their combination with **Zyprexa Velotab** may increase the risk of serious gastrointestinal side effects resulting from decreased gastrointestinal motility. Concomitant treatment with these drugs and olanzapine should be used with caution.

Use of this medicine and food

Zyprexa Velotab may be taken with or without food.

Use of this medicine and alcohol consumption

Avoid drinking alcohol while taking **Zyprexa Velotab**. Drinking alcohol while taking **Zyprexa Velotab** may make you drowsier compared to taking **Zyprexa Velotab** without alcohol.

Pregnancy, breastfeeding, and fertility

Pregnancy

Consult the doctor or pharmacist before taking this medicine.

Consult the doctor if you are pregnant or planning to get pregnant. It is not known whether **Zyprexa Velotab** harms the fetus. Newborns may develop a withdrawal syndrome if the mother has taken the medicine during the last trimester (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.

Breastfeeding

Consult the doctor if you are breastfeeding or planning to breastfeed. The drug passes into breast milk. There are reports of excessive calm and drowsiness, irritability, poor feeding, and extrapyramidal symptoms (tremors and abnormal muscle movements) in infants exposed to olanzapine. Infants exposed to olanzapine should be monitored for these symptoms.

There is no information on the effects of olanzapine on milk production.

Talk to the doctor about the best way to feed your baby if you are taking **Zyprexa Velotab**.

Fertility

Treatment with **Zyprexa Velotab** may cause an increase in blood prolactin levels, which can lead to reversible harm to fertility in women of childbearing age and in men.

Driving and using machines

The use of this medicine may cause drowsiness and affect your decision-making skills, sharp thinking or quick response, and therefore requires caution when driving a vehicle, operating dangerous machinery and any activity that requires alertness. Avoid any activity such as these until you understand how **Zyprexa Velotab** affects you.

Important information about some of the ingredients of this medicine

Zyprexa Velotab 5/10 mg contains aspartame 0.6/0.8 mg (respectively) in each soluble tablet. Aspartame is a source of phenylalanine. It may harm a patient who has phenylketonuria, a rare genetic disorder in which phenylalanine accumulates, resulting in the body not being able to clear it properly.

Zyprexa Velotab contains parahydroxybenzoate - may cause allergic reactions (late reactions are possible).

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 about the dose and manner of treatment with the drug.
- The dosage and manner of treatment will be determined only by the doctor. Your doctor may need to change the dose until he finds the right dose for you.
- **Do not exceed the recommended dose.**
- Make sure your hands are dry. Separate one unit from the blister package and carefully peel off the cover. Do not push the tablet. The tablet should be removed and placed whole, in the mouth, immediately after peeling off the cover. The tablet dissolves in saliva quickly, so it can be easily swallowed with or without a drink.
- **Zyprexa Velotab** is intended for adults over the age of 18.
- **Zyprexa Velotab** may be taken with or without food.
- There is no information on the preparation when it is crushed or split. Therefore, do not chew, crush, or split the tablet!
- There is no information on the preparation when used with a nasogastric tube.
- **If you have accidentally taken a higher dose**, you may feel drowsy, experience impaired speech, aggressiveness or restlessness, rapid heart rate, tremor, muscle spasms, muscle movement impairment, and reduced levels of consciousness (from drowsiness to coma).

If you have taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a doctor or the hospital Emergency Room and bring the medicine package with you.

- **If you forgot to take the medicine** at the required time, take the medicine when you remember. If it is close to the time of taking the next dose, skip this dose and take the dose at the usual time. Do not take a double dose.
- 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.
- **To avoid serious side effects, do not stop taking Zyprexa Velotab abruptly. If you need to stop taking Zyprexa Velotab, the doctor will instruct you on how to do it.**
- **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.**

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

4. SIDE EFFECTS

As with any medicine, the use of **Zyprexa Velotab** 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 Velotab may cause serious side effects:

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

The doctor should perform blood tests to regularly monitor your blood glucose levels before and during treatment with **Zyprexa Velotab**. In patients who do not have diabetes, the high blood glucose levels sometimes go away when treatment with **Zyprexa Velotab** is stopped. Patients with diabetes and some patients who did not have diabetes at the start of treatment with **Zyprexa Velotab** should take medication to lower their blood glucose even after stopping treatment with **Zyprexa Velotab**.

If you have diabetes, follow the doctor's instructions regarding how often to test blood glucose levels while taking **Zyprexa Velotab**.

Consult a doctor if you experience one of the symptoms of high blood glucose levels:

- increased thirst
- increased urination
- increased appetite
- feelings of weakness or fatigue
- feelings of nausea
- feelings of confusion
- fruity breath odor
- **Increase in lipid levels (cholesterol and triglyceride) in the blood** may occur in patients who are being treated with **Zyprexa Velotab**. The doctor must perform blood tests for cholesterol and lipid levels before the beginning and during treatment even if you do not have any symptoms.
- **Weight gain** is very common in patients who are taking **Zyprexa Velotab**. Some patients experience extreme weight gain. Close monitoring of weight is therefore required. Consult the doctor regarding weight maintenance, such as a healthy and balanced diet and exercise.
- **Increased incidence of stroke or "mini stroke" - Transient Ischemic Attack (TIA) in elderly people with dementia-related psychosis** (elderly people who

are experiencing loss of touch with reality due to confusion and memory loss).
Zyprexa Velotab is not approved for use in these patients.

- **Neuroleptic malignant syndrome** - a rare but serious condition which may occur in patients who are taking antipsychotic medicines, including **Zyprexa Velotab**. Neuroleptic malignant syndrome may cause death and requires hospitalization. Refer to the doctor immediately if you become very ill and experience any of the following symptoms:
 - high fever
 - increased sweating
 - stiff muscles
 - confusion
 - changes in your breathing, heart rate, and blood pressure.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)**. This side effect may occur with **Zyprexa Velotab**. This side effect may include rash, fever, swollen glands, and the involvement of other internal organs such as the liver, kidneys, lungs, and heart. This side effect can sometimes lead to death, so tell the doctor immediately if you experience any of these symptoms.
- **Tardive dyskinesia** - a condition that causes involuntary movements in the body which you can't control. The movements are usually of the face and tongue. This side effect may continue even after you stop taking **Zyprexa Velotab**. This side effect may also start after you stop taking **Zyprexa Velotab**. Tell the doctor if you are having involuntary body movements.
- **Drop in blood pressure when changing position including symptoms such as dizziness, fast or slow heart rate, or fainting**. This side effect occurs mainly at the beginning of taking this medicine.
- **Difficulty swallowing which may cause food or drink to get into your lungs**.
- **Seizures** - tell the doctor if you experience a seizure while using **Zyprexa Velotab**.
- **Problems regulating body temperature** - you may experience a large increase in body temperature, for example when exercising a lot or when you are in a very hot place. It is important to drink water to prevent dehydration. See the doctor immediately if you become very ill and have symptoms of dehydration:
 - excessive sweating or lack of sweat
 - dry mouth
 - feeling very hot
 - increased thirst
 - urinary retention

Additional side effects

Very common side effects:

Weakness, lack of energy, dry mouth, constipation, indigestion, drowsiness, dizziness, accidental injury, insomnia, parkinsonism, weight gain, low blood pressure when transitioning from lying down to sitting up, and elevated prolactin levels.

Common side effects:

Fever, tremors, back pain, chest pain, pain in your limbs, joint pain, increased heart rate, high blood pressure, vomiting, physical restlessness, increased appetite, behavioral changes, increased triglyceride and cholesterol levels in the blood, subcutaneous bleeding manifested as patches on the skin, peripheral edema, abnormal walking, stiff muscles, speech impediment, runny nose, cough, lazy eye, inflammation of the esophagus, drowsiness, urinary incontinence, urinary tract infection, increased blood levels of alkaline phosphatase, discharge of milk from the breasts, enlarged breasts in men, memory impairment, paresthesia, uplifted mood (euphoria), shortness of breath, dry skin, acne, visual impairment, menstrual pain and vaginal inflammation in women, hard stools or rarely passing stools, depression, lowered amount of certain types of white blood cells, thirst, confusion, sweating, low blood pressure, personality disorders, increased salivation.

Uncommon side effects:

Chills, facial edema, sensitivity to light, attempted suicide, apathy, clouded consciousness, 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, torpidity, nose bleeding, hair loss, dry eyes, changes in visual focus (accommodation), impotence, changes in the menstrual cycle (such as no menstruation, decrease/increase in menstrual bleeding, heavy menstrual bleeding, intermenstrual bleeding), urinary 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:

Hangover effect, intestinal obstruction, fatty liver, osteoporosis, coma, pulmonary edema, dilated pupils, sudden death, chills, and fever.

Side effects of unknown frequency:

Allergic reaction (such as: anaphylactic reaction, swelling of the face or throat (angioedema), itching, rash), diabetes-related coma, diabetic ketoacidosis, side effects that may occur when stopping treatment (nausea, vomiting, and sweating), jaundice, pancreatitis and hepatitis, liver injury, restless legs syndrome, painful and prolonged erection (priapism), painful muscle injury (rhabdomyolysis), venous thrombosis, stuttering, accumulation of bile acids, bowel incontinence, and sleepwalking.

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 an online form for reporting side effects, or by entering the following link: <https://sideeffects.health.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 sight and 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.
- **Storage conditions:** Store at a temperature below 25°C.

6. ADDITIONAL INFORMATION:

In addition to the active ingredient, Zyprexa Velotab tablets also contain:

Gelatin, mannitol, aspartame, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and purified water.

What does the medicine look like and what are the contents of the package:

Blister packs of 14, 28 yellow round tablets.

Not all pack sizes may be marketed.

License holder and address:

Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petah Tikva.

Manufacturer name and address:

CHEPLAPHARM Schweiz GmbH, Binningen, Switzerland.

Revised in July 2025.

Registration numbers in the National Drug Registry of the Ministry of Health:

Zyprexa Velotab 5 mg: 130-75-30740-00

Zyprexa Velotab 10 mg: 130-76-30741-00

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