PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Olanzapine ODT Teva 5 mg Orodispersible tablets

Composition:
Each orodispersible tablet contains:
Olanzapine 5 mg

Olanzapine ODT Teva 10 mg Orodispersible tablets

Composition:
Each orodispersible tablet contains:
Olanzapine 10 mg

For information about inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar to yours.

Essential information about the medicine:
Antipsychotics (like **Olanzapine ODT Teva**) may increase the risk of death in adults who suffer from confusion, memory loss, and loss of touch with reality (dementia associated with psychosis). The medicine is not intended for treatment of psychosis in adults who suffer from dementia.

Olanzapine ODT Teva is intended for adults above the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Acute and maintenance treatment of schizophrenia.
Olanzapine ODT Teva is indicated for management of the manifestations of psychotic disorders.
Olanzapine ODT Teva 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 **Olanzapine ODT Teva** is indicated for the prevention of recurrence in patients with bipolar disorder.
Combination therapy in Bipolar I Disorder:
The combination of **Olanzapine ODT Teva** 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include hearing voices, seeing things that are not there, having beliefs that are not true, being suspicious, and being withdrawn.

The symptoms of bipolar I disorder include alternating periods of depression and high or irritable mood, increased activity and restlessness, racing thoughts, talking fast, changes in appetite, impulsive behavior, and a decreased need for sleep.

The symptoms of treatment-resistant depression include decreased mood, decreased interest, increased guilty feelings, decreased energy, decreased concentration, changes in appetite, and suicidal thoughts or behavior.

2. BEFORE USING THE MEDICINE:

Do not use this medicine if:
- You are sensitive (allergic) to olanzapine or to any of the other ingredients in the medicine (see section 6: 'Further information').
- For specific information about contraindications for lithium or valproate use please read the contraindications section in the patient leaflets enclosed with those medicines.

Special warnings regarding use of the medicine:
- **Olanzapine ODT Teva** interferes with the body's ability to reduce body temperature. Avoid situations in which an 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.
- **Olanzapine ODT Teva** may cause low blood pressure when rising from lying down to sitting up. The symptoms include: dizziness, rapid or slow heart rate, and even fainting in some patients. This effect usually occurs at the beginning of treatment.
- **Olanzapine ODT Teva can cause sleepiness, low blood pressure when rising from lying down to sitting up, and motor and sensory instability which may cause falls resulting in fractures and other injuries.** Use with caution and considerweigh the risk/benefit in patients with a medical history or who are taking medicines that may increase the risk of falls.
- Weight gain has been observed in patients taking **Olanzapine ODT Teva**. Weight should be monitored regularly.
- Monitor blood sugar and lipid levels since **Olanzapine ODT Teva** may cause an increase in these measurements.
- 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 monitoring. **Olanzapine ODT Teva** may cause a decrease in the levels of white blood cells. Stopping **Olanzapine ODT Teva** treatment should be considered on first appearance of any symptom of this condition. Patients suffering from reduced levels of white blood cells must be monitored for fever or other symptoms indicatingof infection or fever. If these symptoms occur, immediately stop your **Olanzapine ODT Teva** treatment.
- Taking **Olanzapine ODT Teva** is not recommended in adults suffering from dementia because of the possibility of severe side effects: falls, sleepiness, peripheral edema, abnormal gait, urinary incontinence, lethargy, weight gain, weakness, fever, pneumonia, dry mouth, visual hallucinations, stroke, and death.
- Patients with schizophrenia or bipolar disorder are at a high risk of attempted suicide. Therefore, these patients must be closely monitored while they are being treated with **Olanzapine ODT Teva**.
- Caution is necessary in patients who currently have or have ever had urinary retention, enlarged prostate gland, constipation, or a history of bowel obstruction, because using **Olanzapine ODT Teva** in these patients can cause effects such as constipation, dry mouth, and fast heart rate (tachycardia). Post-marketing experience of using this medicine has shown that the risk of serious side effects (including cases of death) increased when using olanzapine in combination with anticholinergic medicine.

Before treatment with Olanzapine ODT Teva, tell your doctor if:
- You suffer, or have suffered in the past, from impaired heart function.
- You suffer, or have suffered in the past, from a stroke or "mini-stroke" (temporary symptoms of stroke).
- You suffer from problems with your liver, gastrointestinal system (such as bowel obstruction).
- You suffer from Alzheimer's, breast cancer.
- You experience thoughts of suicide or of hurting yourself. If this happens, immediately see a doctor or go to an emergency room.
- You suffer, or have suffered in the past, from enlargement of the prostate gland.
- You suffer, or have suffered in the past, from seizures, diabetes or high blood sugar levels, high or low blood pressure, high blood levels of cholesterol or triglycerides.
- You exercise a lot or are in hot places often.
- You have a history of substance abuse.
- You suffer from phenylketonuria – **Olanzapine ODT Teva** contains phenylalanine (aspartame).
- You are sensitive to lactose – **Olanzapine ODT Teva** contains lactose and may cause sensitivity in people sensitive to lactose.
- You have any other medical problem.

Smoking:
If you are a smoker, tell your doctor before starting treatment with this medicine.

Children and adolescents:
Olanzapine ODT Teva is intended for adults over 18 years old.

Tests and follow-up:
- Your blood sugar levels must be monitored when you start and during treatment, especially if you have diabetes or borderline sugar levels (100-126 mg/dL fasting).
- Lipid levels (cholesterol and triglycerides) in the blood must be monitored especially in patients with lipid level disorders or patients with risk factors for developing these disorders. Your doctor must perform blood tests for blood lipid levels when you start and during treatment even if you are not experiencing any symptoms.
- Weight gain is a common side effect of treatment with **Olanzapine ODT Teva**. Take this into account before you start treatment and have your weight monitored regularly.
- In patients with a medical history of low levels of white blood cells, white blood cell levels must be monitored during the first months of treatment. Stopping **Olanzapine ODT Teva** treatment should be considered on first appearance of any symptom indicating a decrease in white blood cell count.

Other medicines and Olanzapine ODT Teva
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Diazepam: Concomitant administration of **Olanzapine ODT Teva** and diazepam may cause low blood pressure when rising from lying down to sitting up (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, medicines for depression and sleep medications, anti-epileptic medicines – care should be taken when these medicines are given together with olanzapine.
- Medicines used to reduce blood pressure – olanzapine may enhance the blood pressure-lowering effect when given together with these medicines.
- Medicines that mimic the action of dopamine (such as levodopa, the medicine for Parkinson's) – olanzapine may inhibit the activity of these medicines.
- Anticholinergic medicines - Combining them with **Olanzapine ODT Teva** may increase the risk of serious side effects in the digestive system that are related to reduced motility of the digestive system.

Using this medicine and food:
Olanzapine ODT Teva can be taken with or without food.

Using this medicine and alcohol consumption:
Avoid consuming alcohol when using **Olanzapine ODT Teva**. Drinking alcohol while you are taking **Olanzapine ODT Teva** may make you sleepier than if you take **Olanzapine ODT Teva** without alcohol.

Pregnancy, breastfeeding, and fertility:
Pregnancy
Consult the doctor or pharmacist before using the medicine.

If you are pregnant or are planning to get pregnant, consult the doctor. It is not known if **Olanzapine ODT Teva** will harm your unborn baby. Newborns may develop withdrawal syndrome if the mother has taken the medicine during the last trimester (the last three months) of pregnancy. Withdrawal syndrome includes the following symptoms: restlessness, tremor, muscle stiffness/weakness, drowsiness, nervousness, respiratory and feeding problems. If your child develops any of the above symptoms, contact your doctor.

Breastfeeding
This medicine passes into breastmilk. Talk to your doctor about the best way to feed your baby if you breastfeedingtake **Olanzapine ODT Teva**.

Fertility
Treatment with **Olanzapine ODT Teva** can cause an increase in blood prolactin level, which can lead to reversible damage to fertility in women of childbearing age.

Driving and using machines:
Using this medicine may make you sleepy, affect your decision making ability, the sharpness of your thinking or your ability to react quickly, so exercise caution while driving a vehicle, operating dangerous machinery or engaging in any activity which requires alertness. Avoid any such activities until you understand how **Olanzapine ODT Teva** affects you.

Important information about some of this medicine's ingredients:
- **Olanzapine ODT Teva** contains lactose and sucrose. If you have been told before by a doctor that you have an intolerance (sensitivity) to certain sugars, consult the doctor before starting treatment with the medicine.
  Sucrose can damage your teeth.
- **Olanzapine ODT Teva** 5 mg contains 2.25 mg aspartame per tablet.
  Olanzapine ODT Teva 10 mg contains 4.5 mg aspartame per tablet.
  Aspartame is a source of phenylalanine. Aspartame may harm you if you have phenylketonuria (PKU) which is a rare genetic disorder in which phenylalanine builds up because the body cannot clear it out properly.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are uncertain about your dosage and the instructions for using the medicine.
- The dosage and treatment regimen will be determined by the doctor only. Your doctor may need to adjust your dosage until the right dosage for you is found.
- **Do not exceed the recommended dose.**
- Take the tablet out with dry hands and with care (to avoid breaking it) and place it in your mouth immediately. The tablet dissolves quickly in saliva, so you can swallow it easily with or without a beverage.
- There is no information about the medicine when it is crushed or split. Therefore, do not crush, split or chew the tablet!
- There is no information about using this medicine with a nasogastric tube.
- **If you have accidentally taken a higher dosage,** you may feel drowsy, experience impaired speech, aggressiveness or restlessness, rapid heart rate and reduced level of consciousness.
  If you took an overdose or if a child has accidentally swallowed some medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the medicine package with you.
- **If you forgot to take this medicine at the required time,** take the medicine when you remember. If it is almost time for the next dose, skip the dose and take the next one at the usual time. Do not take a double dose.
- Adhere to the treatment regimen as recommended by the doctor.
- Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your doctor.
- **To prevent serious side effects, do not stop taking Olanzapine ODT Teva suddenly. If you need to stop taking Olanzapine ODT Teva, your doctor will tell you how to do this.**
- **Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult your doctor or pharmacist.**

4. SIDE EFFECTS

As with any medicine, use of Olanzapine ODT Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Olanzapine ODT Teva 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). **Olanzapine ODT Teva** is not intended for use in elderly patients with dementia.
2. **Increase in blood sugar levels (hyperglycemia)** may occur in patients suffering from diabetes and in patients who are not suffering from diabetes. Increase in blood sugar levels may cause:
   • ketoacidosis – increased level of acid in the blood due to build-up of ketones • coma • death
   Your doctor must perform blood tests to test your blood sugar levels before starting and during treatment with **Olanzapine ODT Teva**. Patients who are not suffering from diabetes may experience an increase in blood sugar levels when stopping **Olanzapine ODT Teva** treatment. Patients suffering from diabetes and some patients who did not suffer from diabetes when they started **Olanzapine ODT Teva** treatment may need a medicine to reduce their blood sugar levels when they stop **Olanzapine ODT Teva** treatment.
   If you suffer from diabetes, your doctor will instruct you how often to have blood tests for blood sugar levels while you are taking **Olanzapine ODT Teva**.
   Contact your doctor if you experience any of the symptoms of high blood sugar level:
   • increased thirst • increased frequency of urination • increased sensation of hunger • weakness and tiredness • nausea • confusion or fruity breath
3. **Increase in blood lipid levels (cholesterol and triglycerides)** may occur in patients taking **Olanzapine ODT Teva**. Your doctor must perform blood tests for blood cholesterol and lipid levels at the beginning of and during treatment even if you are not experiencing any symptoms.
4. **Weight gain** is very common in patients who are taking **Olanzapine ODT Teva**. Some patients experience extreme weight gain, so your doctor must weigh you during the course of treatment with **Olanzapine ODT Teva**. Talk to your doctor about ways to control weight gain, such as eating a healthy, balanced diet, and exercising.
5. **Increased frequency of stroke or "mini-stroke" – transient ischemic attack (TIA) in elderly people with psychosis associated with dementia** (elderly people who are suffering from loss of touch with reality due to confusion and memory loss). **Olanzapine ODT Teva** is not approved for use in these patients.
6. **Neuroleptic malignant syndrome** – a rare but very serious condition which may occur in patients who are taking antipsychotic medicines, including **Olanzapine ODT Teva**. Neuroleptic malignant syndrome may cause death and requires hospitalization. Contact your doctor immediately if you experience:
   • high fever • increased sweating • stiff muscles • confusion • changes in your breathing, heartbeat and blood pressure
7. **Drug reaction with eosinophilia and systemic symptoms (DRESS).** This effect may include: rash, fever, swollen glands and involvement of other internal organs such as: liver, kidneys, lungs, and heart. This effect can sometimes be fatal, so tell your doctor immediately if you experience any of these signs.
8. **Tardive dyskinesia** – a condition that causes involuntary movements, mainly of the face or tongue. This effect may continue even after you stop treatment with **Olanzapine ODT Teva**. This effect may also start after you stop treatment with **Olanzapine ODT Teva**.
   Tell the doctor if you are having involuntary body movements.
9. **Drop in blood pressure when changing position**, including symptoms such as dizziness, fast or slow heartbeat or fainting. This side effect happens mainly when you start taking this medicine.
10. **Difficulty swallowing** which may cause food or drink to reach the lungs.
11. **Seizures** – tell your doctor if you experience seizures during the course of treatment with **Olanzapine ODT Teva**.
12. **Problems regulating body temperature** – you may suffer from 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. Contact your 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, (low energy), dry mouth, constipation, indigestion, drowsiness, dizziness, accidental injuries, insomnia, parkinsonism.

Common side effects:
fever, tremor, back ache, chest pain, limb pain, joint pain, increased heart rate, high blood pressure, vomiting, physical restlessness, increased appetite, behavioral changes, increased blood triglyceride levels, weight gain, low blood pressure when rising 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, impaired memory, paresthesia, euphoria, shortness of breath, dry skin, acne, impaired vision, menstrual pain and vaginal inflammation in women, hard stools or passing stools infrequently.

Uncommon side effects:
chills, facial edema, sensitivity to light, attempted suicide, stroke, vasodilatation, nausea, vomiting, tongue edema, reduced white blood cell levels, reduced 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 focus (accommodation), impotence, changes in the menstrual cycle, (such as no periods, decreased/increased menstrual bleeding, heavy menstrual bleeding), urinary retention, urinary frequency and urgency, large urine volume, breast pain, dystonia (spasm of the neck muscles, difficulty swallowing, difficulty breathing, tongue protrusion), abdominal distension, and death due to diabetes.

Side effects occurring rarely:
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, diabetic ketoacidosis, side effects that may occur when treatment is stopped (nausea, vomiting, sweating), jaundice, pancreatitis and hepatitis, liver injury, increased salivation, 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 experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health homepage (www.health.gov.il) which directs you to the online form for reporting side effects, or by following the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Prevent poisoning! This medicine, and all other medicines, must be kept in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C. Store in the original package to protect from light.**

6. FURTHER INFORMATION

In addition to the active ingredient, Olanzapine ODT Teva tablets also contain:
Mannitol, lactose monohydrate, crospovidone (Type B), hydroxypropyl cellulose (low-substituted), magnesium stearate (vegetable), aspartame (E 951), lemon flavor (contains sucrose).

What the medicine looks like and contents of the package:
Olanzapine ODT Teva 5 mg – a plain and smooth, round, yellow, 8-mm-diameter, tablet that is convex on both sides.
Olanzapine ODT Teva 10 mg – a plain and smooth, round, yellow, 10-mm-diameter tablet that is convex on both sides.
Packs contain 28 or 30 tablets; not all pack sizes may be marketed.

Name and address of license holder: Abic Marketing Ltd. (Teva Group), P.O.B. 8077, Netanya.

Name and address of manufacturer:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva.

This leaflet was revised in November 2020

Registration numbers of the medicine in the Ministry of Health National Drug Registry:
Olanzapine ODT Teva 5 mg: 157.15.34598
Olanzapine ODT Teva 10 mg: 157.16.34591

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