

PART III: CONSUMER INFORMATION

**Pr OLANZAPINE ODT
(olanzapine orally disintegrating tablets)**

This leaflet is part III of a three-part "Product Monograph" published when OLANZAPINE ODT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OLANZAPINE ODT. Contact your doctor or pharmacist if you have any questions about the drug.

Keep this information with your medicine in case you need to read it again.

ABOUT THIS MEDICATION

The name of your medicine is OLANZAPINE ODT and your doctor has prescribed it to help relieve the symptoms that are bothering you. OLANZAPINE ODT can help to control your symptoms and reduce the risk of relapse. Although OLANZAPINE ODT cannot cure your symptoms, it can help you keep them under control as you continue your treatment.

What the medication is used for:

OLANZAPINE ODT is used to treat symptoms of schizophrenia and related psychotic disorders as well as those of bipolar disorder.

Your doctor may have prescribed OLANZAPINE ODT for another reason. Ask your doctor if you have any questions about why OLANZAPINE ODT has been prescribed for you.

What it does:

OLANZAPINE ODT belongs to a group of medicines called antipsychotics. OLANZAPINE ODT is used to treat symptoms of schizophrenia and related psychotic disorders as well as those of bipolar disorder. Schizophrenia may cause symptoms such as hallucinations (e.g. hearing, seeing, or sensing things which are not there), delusions, unusual suspiciousness, feeling withdrawn, lack of emotions. People with schizophrenia may also feel depressed, anxious or tense. Signs and symptoms of bipolar mania include but are not limited to: feeling invincible or all powerful, inflated self-esteem, racing thoughts, easily lose your train of thought, overreaction to what you see or hear, misinterpretation of events, speeded-up activity, talking very quickly, talking too loudly, or talking more than usual, decreased need for sleep, and poor judgment.

When it should not be used:

Do not use OLANZAPINE ODT if you have had an allergic reaction to olanzapine or any of the ingredients listed in the "Nonmedicinal Ingredients" section of this leaflet. Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

What the medicinal ingredient is:

OLANZAPINE ODT contains the active ingredient called olanzapine.

What the nonmedicinal ingredients are:

OLANZAPINE ODT contains the following inactive ingredients: aspartame, colloidal anhydrous silica, crospovidone, mannitol, sodium stearyl fumarate and sorbitol crystalline.

What dosage forms it comes in:

OLANZAPINE ODT is available in 5 mg, 10 mg, 15 mg and 20 mg tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
 Studies with various medicines of the group to which olanzapine belongs, including OLANZAPINE ODT, when used in elderly patients with dementia have been associated with an increased rate of death. OLANZAPINE ODT is not indicated in elderly patients with dementia.

Before starting OLANZAPINE ODT and to get the best possible treatment, be sure to tell your doctor if you:

- are pregnant or plan to become pregnant
- are breast feeding or plan on breast feeding
- have had an allergic reaction to any medicine which you have taken previously to treat your current condition
- have diabetes or a family history of diabetes
- have a history of any problems with the way your heart beats or have any heart problems
- have a history of stroke or high blood pressure
- have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, or take oral contraceptives ("The Pill").
- are a smoker
- have ever had blackouts or seizures
- are taking any other medicines (prescriptions or over-the-counter medicines)
- drink alcoholic beverages or use drugs
- exercise vigorously or work in hot or sunny places
- have a history of liver problems, hepatitis, or yellowing of the eyes and skin (jaundice)
- have prostate problems
- have intestinal congestion (paralytic ileus)
- have raised pressure within the eye (glaucoma)
- cannot take phenylalanine because OLANZAPINE ODT contains aspartame, a source of phenylalanine.

It is important for your doctor to have this information before prescribing your treatment and dosage.

Effects on Newborns:

In some cases, babies born to a mother taking olanzapine during

pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

INTERACTIONS WITH THIS MEDICATION

Tell all doctors, dentists and pharmacists who are treating you that you are taking OLANZAPINE ODT.

Tell your doctor or pharmacist that you are taking OLANZAPINE ODT before you start taking any new medicines.

A combination of OLANZAPINE ODT with the following medicines might make you feel drowsy:

- medicines taken for anxiety or to help you sleep
- medicines taken for depression.

The effects of alcohol could be made worse while taking OLANZAPINE ODT. It is recommended that you DO NOT drink alcohol while taking OLANZAPINE ODT.

You should tell your doctor if you are taking fluvoxamine (antidepressant), ketoconazole (antifungal), or ciprofloxacin (antibiotic), as these medicines may lead to higher concentrations of olanzapine in your blood.

You should also tell your doctor if you are taking carbamazepine as it may lead to lower concentrations of olanzapine in your blood, making OLANZAPINE ODT less effective.

Only take other medicines while you are on OLANZAPINE ODT if your doctor tells you that you can. DO NOT give OLANZAPINE ODT to anyone else. Your doctor has prescribed it for you and your condition.

PROPER USE OF THIS MEDICATION

Usual dose:

The most important thing about taking OLANZAPINE ODT is to take it the way your doctor has prescribed – the right dose, every day. Your doctor has decided on the best dosage for you based on your individual situation and needs. Your doctor may increase or decrease your dose depending on your response.

Although OLANZAPINE ODT cannot cure your condition, it can help relieve your symptoms. If your symptoms improve or disappear, it is probably because your treatment is working. Studies have shown that, after coming off medication, a relapse of symptoms occurs in about 2 out of 3 patients and is more than double that of patients staying on their medication. That is why it is so important to keep taking OLANZAPINE ODT, even after your symptoms have improved or disappeared. OLANZAPINE ODT should be taken for as long as you and your doctor believe it is helping you.

Proper Handling Instructions

OLANZAPINE ODT should be handled carefully with dry hands and direct contact with the hands should be minimized if possible.

Follow the instructions below:

1. Gently push the tablet out through the blister foil on top.
2. With dry hands, put the tablet directly into your mouth. It will begin to dissolve in your mouth within a few seconds. You can also place the tablet directly into a full glass of water, milk, coffee, orange juice or apple juice. Stir and drink all of the contents immediately.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Show the health care practitioner your bottle of tablets. Do this even if there are no signs of discomfort or poisoning. The most common signs if you have taken too much olanzapine are drowsiness and slurred speech.

Missed Dose:

Take your prescribed dose at the same time each day. If you miss a dose of OLANZAPINE ODT by a few hours, take the dose when you remember. If most of the day has passed, wait until your next scheduled dose and try not to miss any more. **Do not take 2 doses at once.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medicines, OLANZAPINE ODT can cause some side effects. These side effects are most likely to be minor and temporary. However, some may be serious and need medical attention. Many of the side effects are dose related, so it is important not to exceed your prescribed dose. The most common side effects of OLANZAPINE ODT are:

- drowsiness
- weight gain
- dizziness
- increased appetite
- fluid retention
- constipation
- dry mouth
- a feeling of restlessness (akathisia)
- decreased blood pressure upon rising from a lying or sitting position

You should also tell your doctor if you notice any symptoms that worry you, even if you think the problems are not connected with the medicine or are not listed here.

Because some people experience drowsiness, you should avoid driving a car or operating machinery until you know how OLANZAPINE ODT affects you. Some people may feel dizzy in the early stages of treatment, especially when getting up from a

lying or sitting position. This side effect usually passes after taking OLANZAPINE ODT for a few days.

After prolonged use in women, medicines of this type can cause milk secretion or changes in the regularity of their monthly period. On rare occasions, after prolonged use in men, medicines of this type have been associated with breast enlargement. As well, abnormal liver function tests have been reported on occasion.

Your doctor should check your body weight before starting OLANZAPINE ODT and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting OLANZAPINE ODT. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

Do not be alarmed by this list of possible side effects. You may not experience any of them. If any of these side effects are experienced, they are usually mild and temporary.

The following table is based on data from placebo-controlled clinical trials and from post-marketing data.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common			
New or worsening constipation		✓	
Uncommon			
Slow heartbeat ¹		✓	
Rare			
Liver inflammation [symptoms of fever, yellow skin or eyes, dark urine, weakness, abdominal pain, nausea, vomiting, loss of appetite, itching] ²		✓*	
Low white blood cell count [symptoms of infection, such as cold, flu-like symptoms, fever, sore throat, as well as weakness or general feeling of unwellness] ²		✓	
Rash ² (see also Allergic Reaction below)	✓		
Seizure [i.e. loss of consciousness with uncontrollable shaking (“fit”)] ²			✓*

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very Rare			
Allergic Reaction [symptoms include skin rash, hives, swelling, difficulty breathing] ²			✓*
Bruise easily, excessive bleeding ²		✓	
High fever, muscle rigidity, rapid heartbeat, profuse sweating, irregular pulse ^{1,2}			✓*
Increased thirst & hunger, frequent urination ^{1,2}		✓	
Muscle twitching or abnormal movements of the face or tongue ²		✓*	
Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations. ²		✓	
Pancreas inflammation [symptoms of severe abdominal pain, fever, nausea, vomiting] ²			✓
Long-lasting (greater than 4 hours in duration) and painful erection of the penis ²			✓
Sudden weakness or numbness in the face, arms, or legs, and speech or vision problems ³			✓*
Very dark (“tea coloured”) urine, muscle tenderness and/or aching ²			✓
Serious skin reactions: (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS]): skin rash or redness developing into widespread rash with blisters and peeling skin, swollen lymph nodes and fever.			✓

¹ Identified from the clinical trial database.

² Identified from adverse events reported after release onto market

³ Identified from data from 5 placebo-controlled trials in elderly patients with dementia-related psychosis.

* If you think you have these side effects, it is important that you seek medical advice from your doctor immediately.

This is not a complete list of side effects. For any unexpected effects while taking OLANZAPINE ODT, contact your doctor or pharmacist.

HOW TO STORE IT

All medicines should be kept out of the reach of children. OLANZAPINE ODT should be stored in its original package at room temperature (between 15°C and 30°C), in a dry place and out of direct light. The expiry date of this medicine is printed on

the label. Do not use the medicine after this date. If your doctor tells you to stop taking OLANZAPINE ODT or you find that they have passed their expiry date, please return any left over medicine to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor at 1-866-236-4076 or emailing quality@sanis.com.

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