

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ZOLINZA®

vorinostat capsules

This Patient Medication Information is written for the person who will be taking ZOLINZA®. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about ZOLINZA®, talk to a healthcare professional.

Serious warnings and precautions box

ZOLINZA® should be prescribed and managed by a doctor experienced with the use of cancer drugs and with treatment of cutaneous T-cell lymphoma.

The following are serious side effects:

- blood clot (venous thromboembolism), which can lead to death
- reduced red blood cells (anemia) and platelets (thrombocytopenia)

What ZOLINZA® is used for:

ZOLINZA® is used in adults for the treatment of a type of cancer called cutaneous T-cell lymphoma. It is used in patients whose cancer:

- is getting worse,
- is not responding to treatment, or
- returns even after undergoing previous treatments for the whole body.

How ZOLINZA® works:

ZOLINZA® blocks the action of histone deacetylases. Histone deacetylases are involved in turning genes 'on' and 'off'. This is expected to lead to a reduction in the growth and division of the T-cells. ZOLINZA® has been shown to slow or stop the growth of cancer cells. It also has been shown to cause the death of cancer cells.

The ingredients in ZOLINZA® are:

Medicinal ingredient: vorinostat.

Non-medicinal ingredients: magnesium stearate, microcrystalline cellulose and sodium croscarmellose. The capsule shell contains gelatin, titanium dioxide and may contain sodium lauryl sulfate.

ZOLINZA® comes in the following dosage form:

Capsules: 100 mg

Do not use ZOLINZA® if:

- you are allergic to any of the ingredients in ZOLINZA® or its container.
- you have severe liver disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZOLINZA®. Talk about any health conditions or problems you may have, including if you:

- have any medical problems
- have diabetes or are pre-diabetic, especially with associated nerve disorders
- have had a blood clot in your lung
- have had a blood clot in a vein (a blood vessel) anywhere in your body
- have liver disease
- have kidney problems
- have QT/QTc prolongation, have a family history of QT/QTc prolongation, or are at risk of developing torsade de pointes. The risk factors include, but are not limited to, the following:
 - you are female;
 - age 65 years or older;
 - have a history or inherited heart rhythm disorders;
 - have history of family who are under 50 years of age experiencing sudden heart arrest;
 - have heart disease;
 - have conditions that affect your nervous system (e.g., stroke, bleeding in the brain, brain injury);
 - have an eating disorder or are following a strict diet;
 - have diabetes;
 - have damage to the nerves that manage body functions such as blood pressure, heart rate.
- have a personal history of fainting spells
- have electrolyte imbalances (e.g., low blood potassium or magnesium levels) or conditions that could lead to dehydration (e.g., vomiting, diarrhea, nausea)
- have had recent bowel surgery or plan on having bowel surgery

Other warnings you should know about:

Driving and using machines:

ZOLINZA® may cause you to faint and feel dizzy. Before you do tasks which may require special attention, wait until you know how you respond to ZOLINZA®.

Monitoring and testing:

Your healthcare professional will monitor your condition by completing:

- blood tests during your treatment to check your:
 - sugar levels

- blood cell counts
- electrolytes levels (e.g., potassium, magnesium and calcium)
- creatinine levels
- an electrocardiogram during your treatment to assess the condition of your heart

Female patients:

- **Pregnancy and birth control:** If you are able to get pregnant:
 - Avoid becoming pregnant while taking ZOLINZA®. It may harm your unborn baby.
 - Use effective birth control while taking ZOLINZA® and for 6 months after the last dose.
- **Breastfeeding:**
 - It is not known if ZOLINZA® passes into breast milk. You should stop breastfeeding once you start treatment with ZOLINZA®.

Male patients:

- Use effective birth control while taking ZOLINZA® if you have a female partner who can become pregnant. Continue to use birth control for 3 months after taking the last dose.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ZOLINZA®:

- medications that interfere with your electrolyte levels (e.g., loop, thiazide, and related diuretics; laxatives and enemas; amphotericin B; high dose corticosteroids)
- other histone deacetylase (HDAC) inhibitors (e.g., valproic acid, divalproex, medicines used to treat seizures and mood disorders)
- warfarin or any other blood thinner medications
- medications that prolong QT/QTc interval. Examples can include:
 - medications used to treat abnormal heart rhythms
 - painkillers
 - antipsychotics
 - antidepressants
 - medications used to treat infections (e.g., antibiotics and antifungals)
 - medications used to treat malaria
 - medications used to treat nausea and vomiting
 - medications used in organ transplant
 - medications used for asthma
 - other cancer drugs

How to take ZOLINZA®:

- Take ZOLINZA® exactly as prescribed by your healthcare professional.
- **Drink at least 2 litres of liquid (8 glasses x 250 mL liquid) every day to reduce the chances of dehydration.**

- Do not open or crush the ZOLINZA® capsule. Swallow capsule whole.
 - If the capsules are broken or crushed, do not touch the capsules or the contents of the capsules.
 - If the contents of a broken capsule get on the skin or in the eyes, wash thoroughly.

Usual dose:

Take 400 mg (four capsules) once a day. Take with food.

Your healthcare professional may prescribe you a lower dose based on your individual treatment needs (for example, if you have liver disease).

Overdose:

If you think you, or a person you are caring for, have taken too much ZOLINZA®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take a double dose of ZOLINZA®.

Possible side effects from using ZOLINZA®:

These are not all the possible side effects you may have when taking ZOLINZA®. If you experience any side effects not listed here, tell your healthcare professional.

The side effects include:

- Stomach and intestine problems such as diarrhea, nausea, vomiting, loss of appetite, constipation, abdominal pain and weight loss
- Tiredness
- Changes in the way things taste and dry mouth
- Hair loss
- Chills
- Dizziness
- Headache
- Muscle spasms (pain and weakness)

ZOLINZA® can cause abnormal urine and blood test results. Your healthcare professional will decide when to perform the tests and interpret the results.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Dyspnea (Difficulty breathing)		√	
Electrical problems with the heart (QT interval prolongation) that could lead to heart rhythm disturbances: fatigue, weakness, dizziness, fainting, being lightheaded or loss of consciousness, irregular heartbeat			√
Pulmonary embolism (Blood clots in the lungs): chest pain, shortness of breath, cough, coughing up blood			√
Anemia (Low red blood cells): feeling tired, appearing pale, getting tired easily, weakness and shortness of breath		√	
Uncommon			
Fainting		√	
Infections of the blood: high fever, chills, headache, confusion, rapid breathing			√
Deep vein thrombosis (Blood clots in the legs, arms): swelling, pain, arm or leg may be warm to the touch and may appear red			√
Gastrointestinal hemorrhage (Bleeding in the digestive tract): Abdominal cramping, dark-colored stool or blood in stool, pale, tiredness, weakness, shortness of breath, vomit with blood			√
Stroke: numbness or weakness of the arms or legs, dizziness or confusion, slurred/loss of speech			√
Dehydration (Dry mouth, excessive thirst): thirst, headache, loss of appetite, feel tired and weak, lack of sweating, decreased blood pressure and urine, dark yellow urine		√	
Thrombocytopenia (Low blood platelets): easy bruising, bleeding		√	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
for longer than usual if you hurt yourself, fatigue and weakness			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15°C – 30°C). Do not store above 30°C (86 °F).

Keep out of reach and sight of children.

If you want more information about ZOLINZA®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website www.merck.ca; or by calling 1-800-567-2594.

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