



Patient Information Sheet

Vorinostat (marketed as Zolinza)

This is a summary of the most important information about Zolinza. For details, talk to your healthcare professional.

What Is Zolinza?

Zolinza is a prescription medicine used to treat a type of cancer called cutaneous T-cell lymphoma (CTCL) in patients when the CTCL gets worse, does not go away, or comes back after treatment with other medicines.

Zolinza has not been studied in children under the age of 18.

What Are The Risks?

The following are the major potential risks and side effects of Zolinza therapy. However, this list is not complete. Tell your healthcare professional right away if you have any of the following symptoms:

- **Blood clots in the legs (deep vein thrombosis)**
 - sudden swelling in a leg
 - pain or tenderness in the leg. The pain may only be felt when standing or walking.
 - increased warmth in the area where the swelling is
 - skin redness or change in skin color
- **Blood clots that travel to the lungs (pulmonary embolus)**
 - sudden sharp chest pain
 - rapid pulse
 - shortness of breath
 - fainting
 - cough with bloody secretions
 - feeling anxious
 - sweating
- **Dehydration** (loss of too much fluid from the body). This can happen if you are having nausea, vomiting or diarrhea and can not drink fluids well.
- **Low blood cell counts:** Your healthcare professional will periodically do blood tests to check your blood counts.
 - **Low red blood cells.** Low red blood cells may make you feel tired and get tired easily. You may look pale, and feel short of breath.
 - **Low platelets.** Low platelets can cause unusual bleeding or bruising under the skin. Talk to your

healthcare professional right away if this happens.

- **High blood sugar** (blood glucose). If you have high blood sugar or diabetes, monitor your blood sugar frequently as directed by your healthcare professional. Tell your healthcare professional right away if your blood sugar is higher than normal.
- **Electrocardiogram abnormality.** An electrocardiogram, or EKG, is a test that records the electrical activity of your heart. Your healthcare professional will check your blood electrolytes and electrocardiogram periodically.
- **The most common side effects** that may occur with Zolinza include: stomach and intestinal problems (including diarrhea, nausea, vomiting, loss of appetite, constipation and weight loss), tiredness, dizziness, headache, changes in the way things taste and dry mouth, muscle aches, hair loss, chills, fever, upper respiratory infection, cough, increase in blood creatinine, swelling in the foot, ankle and leg and itching.

What Should I Tell My Healthcare Professional?

Before you start taking Zolinza, tell your healthcare professional if you:

- have any allergies
- have had a blood clot in your lung (pulmonary embolus)
- have had a blood clot in a vein (a blood vessel) anywhere in your body (deep vein thrombosis)
- have nausea, vomiting, or diarrhea
- have high blood sugar or diabetes
- have heart problems
- are pregnant or plan to become pregnant. Zolinza may harm your unborn baby. Zolinza has not been studied in pregnant women. If you use Zolinza during pregnancy, tell your healthcare professional immediately.
- are breast-feeding or plan to breast-feed. It is not known if Zolinza will pass into your breast milk. Talk to your healthcare professional about the best way to feed your baby while you are taking Zolinza.

Can Other Medicines Or Food Affect Zolinza?

Tell your healthcare professional about all the medicines you take including prescription and non-prescription

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov





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medicines, vitamins, and herbal supplements. Some medicines may affect how Zolinza works or Zolinza may affect how your other medicines work.

Especially tell your healthcare professional if you take:

- Valproic acid: a medicine used to treat seizures. Your healthcare professional will decide if you should continue to take valproic acid and may want to test your blood more frequently.
- Coumadin: (warfarin) or any other blood thinner. Ask your healthcare professional if you are not sure if you are taking a blood thinner. Your healthcare professional may want to test your blood more frequently.

Know the medicines you take. Keep a list of them with you to show your healthcare professional.

How Should I Take Zolinza?

- Take Zolinza exactly as your healthcare professional tells you to.
- Your healthcare professional will tell you how many Zolinza capsules to take and when to take them.
- Swallow each capsule whole. Do not chew or break open the capsule. If you can't swallow Zolinza capsules whole, tell your healthcare professional. You may need a different medicine.
- Take Zolinza with food.
- If Zolinza capsules are accidentally opened or crushed, do not touch the capsules or the powder contents of the capsules. If the powder from an open or crushed capsule gets on your skin or in your eyes, wash the contacted area well with plenty of plain water. Call your healthcare professional.

- Drink at least eight 8-ounce glasses of liquids every day while taking Zolinza. Drinking enough fluids may help to decrease the chances of losing too much fluid from your body (dehydration) especially if you are having symptoms such as nausea, vomiting or diarrhea while taking Zolinza.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is almost time for your next dose, just skip the missed dose. Just take the next dose at your regular time. Do not take two doses of Zolinza at the same time.
- If you take too much Zolinza, call your healthcare professional, local emergency room, or poison control center right away.
- Your healthcare professional will check your blood cell counts, blood sugar, and other chemistries every two weeks for the first two months of your treatment with Zolinza and then monthly. Your healthcare professional may decide to do other tests to check your health as needed.
- If you have high blood sugar (hyperglycemia) or diabetes, continue to monitor your blood sugar as your healthcare professional tells you to. Your healthcare professional may need to change your diet or medicine to help control your blood sugar while you take Zolinza. Be sure to tell your healthcare professional if you are unable to eat or drink normally due to nausea, vomiting or diarrhea.

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