

**Patient Information**  
**ZOLINZA® (zo LINZ ah)**  
**(vorinostat)**  
**Capsules**

Read the patient information that comes with ZOLINZA<sup>®</sup> before you start taking it and each time you get a refill. There may be new information. This leaflet is a summary of the information for patients. Your doctor or pharmacist can give you additional information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

**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.

**Who should not take ZOLINZA?**

Do not take ZOLINZA if you have severe liver disease.

**What should I tell my doctor before taking ZOLINZA?**

**Tell your doctor about all of your medical conditions, including 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 liver disease
- Have high blood sugar or diabetes
- 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 doctor immediately.
- Are breast-feeding or plan to breast-feed. It is not known if ZOLINZA will pass into your breast milk. Talk to your doctor about the best way to feed your baby while you are taking ZOLINZA.

**Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.** Some medicines may affect how ZOLINZA works, or ZOLINZA may affect how your other medicines work. **Especially tell your doctor if you take:**

- **Valproic acid:** a medicine used to treat seizures. Your doctor will decide if you should continue to take valproic acid and may want to test your blood more frequently.
- **COUMADIN<sup>®</sup> (warfarin) or any other blood thinner.** Ask your doctor if you are not sure if you are taking a blood thinner. Your doctor may want to test your blood more frequently.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

**How should I take ZOLINZA?**

- Take ZOLINZA exactly as your doctor tells you to.

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- Your doctor 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 doctor. 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 doctor.
- **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 doctor, local emergency room, or poison control center right away.
- Your doctor will check your blood cell counts, blood sugar, blood electrolytes, and other chemistries every two weeks for the first two months of your treatment with ZOLINZA and then monthly. Your doctor 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 doctor tells you to. Your doctor may need to change your diet or medicine to help control your blood sugar while you take ZOLINZA. Be sure to tell your doctor if you are unable to eat or drink normally due to nausea, vomiting or diarrhea.

#### **What are the possible side effects of ZOLINZA?**

ZOLINZA may cause **serious side effects**. Tell your doctor 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
  - shortness of breath
  - cough with bloody secretions
  - sweating
  - rapid pulse
  - fainting
  - feeling anxious
- **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.
- **Changes in blood tests:** Your doctor will periodically do blood tests to check your blood counts and electrolytes.
  - **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 doctor 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 doctor. Tell your doctor right away if your blood sugar is higher

than normal.

In addition, the most common side effects 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**
- **Itching**

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ZOLINZA. For more information, ask your doctor or pharmacist.

### **General information about ZOLINZA**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ZOLINZA for a condition for which it was not prescribed. Do not give ZOLINZA to other people, even if they have the same symptoms you have. It may harm them.

### **Keep ZOLINZA and all medicines out of the reach of children.**

This leaflet summarizes the most important information about ZOLINZA. If you would like to know more information, talk to your doctor. You can ask your doctor or pharmacist for information about ZOLINZA that is written for health professionals.

### **What are the ingredients in ZOLINZA?**

**Active ingredient:** vorinostat

**Inactive ingredients:** microcrystalline cellulose, sodium croscarmellose and magnesium stearate. The inactive ingredients in the capsule shell are titanium dioxide, gelatin, and sodium lauryl sulfate.

### **How should I store ZOLINZA?**

Store ZOLINZA at room temperature, 68° F to 77° F (20° C to 25° C).

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