

Patient Information
ZOLINZA® (zo LINZ ah)
(vorinostat)
capsules

What is ZOLINZA?

ZOLINZA is a prescription medicine for a type of cancer called cutaneous T-cell lymphoma (CTCL), which is a blood cell cancer that affects your skin. ZOLINZA is used when your CTCL gets worse, does not go away, or comes back after you have taken other medicines.

What you need to know about ZOLINZA

- Before you take this medicine, be sure you understand what it is used for and how to take it safely.
- Keep this information.
- If you have questions about this medicine, ask your doctor or pharmacist.
- Every time you get a refill, look at the Patient Information. There may be new information.

It is not known if ZOLINZA is safe and effective in children.

Should I take ZOLINZA?

Pregnancy

- ZOLINZA has not been studied in pregnant women. It can hurt your baby while you are pregnant.
- Women of childbearing potential (women who can become pregnant and bear children) should use contraception while taking ZOLINZA and for up to 6 months after the last dose. Please speak with your doctor.
- Men who have female partners who can become pregnant and bear children, should use contraception while taking ZOLINZA and for up to 3 months after taking the last dose. Please speak with your doctor.

Breastfeeding

- We do not know if ZOLINZA can pass into breast milk.
- Women should not breastfeed while using ZOLINZA and for up to 1 week after the last dose. Please speak with your doctor.

Diabetes

- If you are taking ZOLINZA and have high blood sugar (hyperglycemia) or diabetes, your doctor may need to change your diet or diabetes medicine to help control your blood sugar.
- Check your blood sugar as often as your doctor tells you to.
- If your blood sugar is higher than normal, call your doctor.
- If you cannot eat or drink like you usually do because you feel sick, vomit, or have diarrhea, call your doctor.

If you have any of these conditions, tell your doctor before taking ZOLINZA:

- a blood clot in your lung (called a Pulmonary Embolus or PE)
- a blood clot in a vein or blood vessel (called Deep Vein Thrombosis or DVT)
- high blood sugar (hyperglycemia) or diabetes
- liver disease
- nausea, vomiting or diarrhea
- any allergies

Are you taking other medicines?

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Other medicines can affect the way ZOLINZA works.

Your doctor may want to do blood tests more often if you take:

- valproic acid, a medicine for seizures
- a blood thinner, like Coumadin[®] (warfarin)

How do I take ZOLINZA?

- Take ZOLINZA exactly as prescribed by your doctor.
- Your doctor will tell you how many capsules to take, and when to take them.
- Take with food.
- Drink 8 glasses of water every day (at least 8 ounces each). This will help to keep you hydrated, especially if you have nausea, vomiting or diarrhea.
- Do not chew or break open the capsule. If you break open or crush a capsule, do not touch the capsule or powder. If the powder gets on your skin or in your eyes, wash your skin or eyes with lots of water right away. Then, call your doctor.
- If you cannot swallow the capsule, tell your doctor. You may need a different medicine.

What if I forget to take 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 and take the next dose at your regular time. Do not take two doses of ZOLINZA at the same time.
- If you are not sure what to do, call your doctor.
- If you take more than your prescribed dose, call your doctor, poison center, or emergency room right away.

ZOLINZA may cause serious side effects

If you have any of the following signs or symptoms, tell your doctor right away.

Signs of a blood clot in your legs- Deep Vein Thrombosis or DVT

- Your leg swells up or feels warm
- Your leg hurts when you stand or walk
- Your leg hurts or feels very tender
- Your skin turns red or changes color

Signs of a blood clot in your lungs- Pulmonary Embolus or PE

- You have sudden, sharp chest pain
- Your heart is beating very fast
- You feel short of breath
- You feel like you might pass out
- You cough up blood
- You feel very anxious
- You start sweating

Signs of losing too much fluid from your body- dehydration

You can become dehydrated if you cannot eat or drink like you usually do. This can happen when you feel sick, vomit, or have diarrhea. Call your doctor if you get any of these signs or symptoms:

- Your mouth is dry
- Your skin is dry
- You are sleepier than usual
- You feel dizzy or lightheaded

Changes in your blood

Your doctor will check your blood during treatment with ZOLINZA. Here is a list of some side effects that may mean you have a change in your blood:

- You feel more tired than usual
- You look pale
- You have bleeding or your skin is bruising easily
- You feel short of breath
- You have high blood sugar (you may feel more hungry or thirsty, you may urinate more often than usual)

Common side effects of ZOLINZA

- | | | | |
|----------------|----------------------------------|--|-------------|
| ▪ Diarrhea | ▪ Not hungry | ▪ Muscle aches | ▪ Cold |
| ▪ Constipation | ▪ Losing weight | ▪ Itchy skin | ▪ Cough |
| ▪ Nausea | ▪ Dry mouth | ▪ Feeling tired | ▪ Chills |
| ▪ Vomiting | ▪ Losing hair | ▪ Feeling dizzy | ▪ Fever |
| | ▪ Change in the way things taste | ▪ Swelling in the foot, ankle, and leg | ▪ Headaches |

If you have any side effect that bothers you or does not go away, tell your doctor.

There may be other side effects to ZOLINZA that are not listed. For information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Where should I keep ZOLINZA?

- Do not let your medicine get really cold or really hot. Keep it at room temperature.
- Keep ZOLINZA and all medicines out of the reach of children.

More information about ZOLINZA

- Medicines are sometimes prescribed for purposes other than those listed in the patient information. 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 condition. It may harm them.
- This Patient Information summarizes the most important information about ZOLINZA. If you would like more information, talk with your doctor or pharmacist. You can ask them for information about ZOLINZA that was written for healthcare professionals. For more information, call the company that makes ZOLINZA at 1-800-622-4477.

What are the ingredients in ZOLINZA?

The active ingredient is: vorinostat

The inactive ingredients are: microcrystalline cellulose, sodium croscarmellose, magnesium stearate, titanium dioxide, gelatin, and sodium lauryl sulfate.

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