

ZOLINZA®

Vorinostat

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZOLINZA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZOLINZA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ZOLINZA is used for

ZOLINZA contains an active ingredient called vorinostat.

ZOLINZA is a new type of anti-neoplastic (anti-cancer) medicine known as a histone deacetylase (HDAC) inhibitor.

ZOLINZA is a medicine used for the treatment of a type of cancer called cutaneous T-cell lymphoma, also called CTCL.

CTCL is a disease in which certain cells of the lymph system develop into cancer cells and affect your skin. The cells are called T-cells. They are the white blood cells which help to fight infection. CTCL usually develops slowly. Patches can first form on the skin and may develop into tumours in the skin. The cancer can continue to spread to large areas

of the skin and to other organs of the body.

ZOLINZA works by slowing or stopping the growth of these cancer cells. ZOLINZA has also been shown to cause the death of cancer cells.

There are many different types of medicines used to treat CTCL.

Your doctor may have prescribed ZOLINZA for another purpose.

Ask your doctor if you have any questions about why ZOLINZA has been prescribed for you.

ZOLINZA is not addictive.

Safety and effectiveness in children and adolescents has not been established.

This medicine is available only with a doctor's prescription.

Before you take ZOLINZA

When you must not take it

Do not take ZOLINZA if:

- **you have an allergy to ZOLINZA or any of the ingredients listed at the end of this leaflet**
- **you have severe liver disease**
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking ZOLINZA, talk to your doctor.

Before you start to take ZOLINZA

Tell your doctor if:

1. you have or have had any medical conditions, especially the following:

- a blood clot in your lung (pulmonary embolus)
- a blood clot in a vein (blood vessel) anywhere in your body (deep vein thrombosis)
- diabetes
- liver disease

2. you currently have nausea, diarrhoea or vomiting

3. you are pregnant or plan to become pregnant

ZOLINZA may harm your unborn baby. Your doctor will discuss the possible risks and benefits of using ZOLINZA during pregnancy.

4. you are breast feeding or plan to breast feed

It is not known if ZOLINZA passes into breast milk. You should stop breast feeding once you start treatment with ZOLINZA.

5. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you start taking ZOLINZA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines that you buy without a

prescription from your pharmacy, supermarket or health food shop. Some medicines and ZOLINZA may interfere with each other. These include:

- Warfarin, or any other blood thinner, used to prevent blood clots
- Other HDAC inhibitors, including sodium valproate

These medicines may be affected by ZOLINZA, may affect how well it works, or may increase the risk of side effects ZOLINZA. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ZOLINZA.

How to take ZOLINZA

How much to take

Take ZOLINZA only when prescribed by your doctor.

The recommended dose 400 mg once each day. Take all 4 capsules (100 mg each) by mouth once a day.

Your doctor may lower your dose, depending on your response

How to take it

Swallow each ZOLINZA capsule whole with a glass of water. Do not chew or break open the capsules.

Take ZOLINZA with food or immediately after food.

Follow directions given to you by your doctor carefully.

They may differ from the information contained in the leaflet.

Ask your doctor or pharmacist for help if you do not understand the instructions on the bottle label.

If you forget to take it

If you miss a dose, take it as soon as you remember.

If it is almost time to your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose of ZOLINZA.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you have trouble remembering to take your capsules, ask your pharmacist for some hints.

How long to take it

Continue to take ZOLINZA as long as your doctor prescribes it.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much ZOLINZA. Do this even if there are no signs of discomfort or poisoning.

While you are using ZOLINZA

Things you must do

Drink plenty of fluids while taking ZOLINZA. You should drink at least eight (8) full glasses of liquids every day (2 litres).

Having enough fluids may help to reduce the chances of dehydration.

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

Tell your doctor immediately if you develop the following:

- Leg swelling, chest pain, or shortness of breath, which are signs of possible serious side effects
- excessive vomiting or diarrhoea

If you are diabetic, tell your doctor immediately if your blood sugar level is high.

ZOLINZA may increase blood sugar levels in some diabetics. Your doctor may need to adjust your diet and/or the dose of your diabetes medicine.

Tell your doctor if you feel that ZOLINZA is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may need to perform regular tests.

Things you must not do

- **Do not give ZOLINZA to anyone else, even if they have the same condition as you.**

Things to be careful of

Be careful driving or operating machinery until you know how ZOLINZA affects you.

There is no information to suggest that ZOLINZA affects your ability to drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZOLINZA.

ZOLINZA helps most people with CTCL, but it may have unwanted side effects. All medicines can have side effects. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Stomach problems including diarrhoea, nausea, vomiting, loss of appetite, constipation, and weight loss
- tiredness
- low blood cell counts (symptoms include; pale appearance,

shortness of breath, unusual bleeding, bruising or bleeding under the skin)

- dehydration
- changes in the way things taste, dry mouth
- muscle aches
- chills
- high sugar levels in the blood (symptoms include; passing urine more often than is normal for you, excessive thirst, blurred vision)
- hair loss

These are the more common side effects of ZOLINZA. Mostly these are mild.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- stroke (symptoms include: numbness or weakness of the arms or legs, headache, dizziness, confusion, difficulty swallowing, slurred or loss of speech)
- fainting
- infections of the blood
- chest pain
- low blood pressure
- blood clots in the legs, arms or lungs
- fever

These are serious side effects. You may need urgent medical attention. Serious side effects have been reported less frequently.

This is not a complete list of all possible side effects. Others side effects may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even it is not on this list.

Tell your doctor if you notice anything else that is making you feel unwell, even it is not on this list.

Ask your doctor or pharmacist if you do not understand anything on this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using ZOLINZA

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep ZOLINZA in a cool dry place where the temperature stays below 30°C. Do not store ZOLINZA or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not touch ZOLINZA capsules if they are broken or crushed, do not touch the contents of the capsule. If the contents of a broken capsule get on the skin or in the eyes, wash thoroughly.

Disposal

If your doctor tells you to stop taking the capsules, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ZOLINZA comes as a white capsule with "568" over "100 mg" printed black ink on the capsule body.

Ingredients

Active ingredient:

- vorinostat 100 mg per capsule

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- Empty Hard Gelatin Capsules Part #G3ICSR0591 Size 3 White Opaque
- OPACODE monogramming ink S-1-17822 BLACK
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ZOLINZA does not contain sucrose, tartrazine or any other azo dyes.

Supplier

ZOLINZA is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A

26 Talavera Road

Macquarie NSW 2113

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