

ZOLINZA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZOLINZA?

Zolinza contains the active ingredient vorinostat. Zolinza is used for the treatment of a type of cancer called cutaneous T-cell lymphoma (CTCL) by slowing or stopping the growth of these cancer cells.

For more information, see Section [1. Why am I using ZOLINZA?](#) in the full CMI.

2. What should I know before I use ZOLINZA?

Do not use if you have ever had an allergic reaction to vorinostat or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZOLINZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZOLINZA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZOLINZA?

- The recommended dose 400 mg once each day.
- Take all 4 capsules by mouth once a day with a full glass of water. Swallow each capsule whole. Do not chew or break open the capsule. Take ZOLINZA with food or immediately after food.

More instructions can be found in Section [4. How do I use ZOLINZA?](#) in the full CMI.

5. What should I know while using ZOLINZA?

Things you should do	<ul style="list-style-type: none">• Drink plenty of fluids while taking ZOLINZA• If you are diabetic, tell your doctor immediately if your blood sugar level is high.
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Things you should not do	<ul style="list-style-type: none"> • Do not touch Zolinza capsule or the contents of the capsule if they are broken or crushed.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how ZOLINZA affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your capsules in the bottle until it is time to take them. • Store it in a cool dry place away from moisture, heat or sunlight

For more information, see Section [5. What should I know while using ZOLINZA?](#) in the full CMI.

6. Are there any side effects?

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) and hair loss.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZOLINZA®

Active ingredient: *Vorinostat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOLINZA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZOLINZA.**

Where to find information in this leaflet:

- [1. Why am I using ZOLINZA?](#)
- [2. What should I know before I use ZOLINZA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZOLINZA?](#)
- [5. What should I know while using ZOLINZA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZOLINZA?

ZOLINZA contains the active ingredient vorinostat.

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

ZOLINZA is 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.

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

ZOLINZA is not addictive.

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

2. What should I know before I use ZOLINZA?

Warnings

Do not use ZOLINZA if:

- you are allergic to vorinostat, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have severe liver disease
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

Check with your doctor if you:

- have any/had other medical conditions, such as:
 - 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
- currently have nausea, diarrhoea or vomiting
- are pregnant or plan to become pregnant
- are breast feeding or plan to breast feed
- have any allergies to any other medicines or any other substances, such as foods, preservatives, or dyes.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

- 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.
- 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Age specific information

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZOLINZA and affect how it works.

- Warfarin or any other blood thinners used to prevent the clots. Your doctor may wish to test your blood more frequently.
- HDAC (histone deacetylase) inhibitors, including sodium valproate, panobinostat, romedepsin and, belinostat.
- Tell your doctor if you are taking valproic acid (a medicine used to treat seizures). It should not be taken with ZOLINZA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZOLINZA.

4. How do I use ZOLINZA?

How much to take

- The recommended dose is 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 ZOLINZA

- Take all 4 capsules by mouth once a day with a full glass of water.
- Swallow each capsule whole. Do not chew or break open the capsule.
- Take ZOLINZA with food or immediately after food.
- Drink plenty of fluids while taking ZOLINZA to reduce the chances of dehydration.
- Follow directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- Continue to take ZOLINZA as long as your doctor prescribes it.

If you forget to use ZOLINZA

ZOLINZA should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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.

If you use too much ZOLINZA

If you think that you have used too much ZOLINZA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZOLINZA?

Things you should do

Drink plenty of fluids while taking ZOLINZA. You should drink at least eight (8) full glasses of liquids every day (2 litres). This reduces the chance 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 should not do

- Do not give ZOLINZA to anyone else, even if they have the same condition as you.
- Do not touch ZOLINZA capsule or the contents of the capsule if they are broken or crushed. If the content of a broken capsule get on the skin or in the eyes, wash thoroughly.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● Stomach problems including:<ul style="list-style-type: none">○ diarrhoea○ nausea○ vomiting○ loss of appetite○ constipation○ weight loss● tiredness● low blood cell counts, symptoms include:<ul style="list-style-type: none">○ 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:	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ○ passing urine more often than is normal for you ○ excessive thirst ○ blurred vision ● hair loss 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● stroke, symptoms include: <ul style="list-style-type: none"> ○ numbness or weakness of the arms or legs ○ headache ○ dizziness ○ confusion ○ difficulty swallowing ○ slurred or loss of speech ● fainting ● chest pain ● low blood pressure ● blood clots in the legs, arms, or lungs 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • fever 	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZOLINZA contains

Active ingredient (main ingredient)	vorinostat
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Other ingredients (inactive ingredients)	microcrystalline cellulose croscarmellose sodium magnesium stearate Empty Hard Gelatin Capsules Part #G3ICARR0591 Size 3 White Opaque OPACODE monogramming ink S-1-17822 BLACK OPACODE monogramming ink S-1-17823 BLACK.
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Do not take this medicine if you are allergic to any of these ingredients.

ZOLINZA does not contain sucrose, tartrazine, or any other azo dyes.

What ZOLINZA looks like

ZOLINZA comes as a white capsule with "568" over "100 mg" printed black ink on the capsule body. (Aust R 156430).

Who distributes ZOLINZA

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Road

Macquarie NSW 2113

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