

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using ZYDELIG?

ZYDELIG contains the active ingredient idelalisib. ZYDELIG is used in combination with other medicines, for the treatment of chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL) in patients whose disease has returned following a period of improvement. ZYDELIG is also used for the treatment of Follicular lymphoma (FL) in patients whose disease no longer responds to other treatments.

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

2. What should I know before I use ZYDELIG?

Do not use if you have ever had an allergic reaction to ZYDELIG 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 ZYDELIG?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZYDELIG 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 ZYDELIG?

- Take ZYDELIG orally twice daily.
- Take the exact amount of ZYDELIG your doctor has prescribed for you.

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

5. What should I know while using ZYDELIG?

Things you should do	<ul style="list-style-type: none">• Tell your doctor right away if you have a fever or any signs of an infection while taking ZYDELIG.• Use a reliable method of contraception to avoid becoming pregnant while you're being treated with ZYDELIG and for 1 month after your last treatment.• Remind any doctor, dentist or pharmacist you visit that you are using ZYDELIG.
Things you should not do	<ul style="list-style-type: none">• Do not breast-feed.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ZYDELIG affects you. You may feel tired after taking ZYDELIG.
Looking after your medicine	<ul style="list-style-type: none">• Keep your ZYDELIG tablets in the bottle with the cap tightly closed until you take them.• Keep ZYDELIG tablets in a cool, dry place where it stays below 30 °C.

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

6. Are there any side effects?

The most common side effects of ZYDELIG are diarrhoea/inflammation of the large intestine, decreased number of white blood cells, infections, rash, fever. ZYDELIG can cause serious infections that may lead to death. Tell your doctor right away if you have a fever or any signs of an infection while taking ZYDELIG.

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.

WARNING: ZYDELIG can cause serious infections that may lead to death. Tell your doctor right away if you have a fever or any signs of an infection while taking ZYDELIG.

If you have the above serious side effect during treatment with ZYDELIG, your doctor may completely stop your treatment, stop your treatment for a period of time, or change your dose of ZYDELIG.

ZYDELIG[®]

Active ingredient(s): *idelalisib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZYDELIG. **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 ZYDELIG.**

Where to find information in this leaflet:

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

1. Why am I using ZYDELIG?

ZYDELIG contains the active substance **idelalisib**. ZYDELIG which belongs to a group of medicines called antineoplastic agents. This medicine blocks the effects of an enzyme called PI3K-delta. It affects the growth of malignant (cancerous) lymphocytes (a type of white blood cell), causing them to die.

ZYDELIG is used to treat Chronic lymphocytic leukaemia/small lymphocytic lymphoma

Chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL) are cancers of the blood which affect a type of white blood cell called lymphocytes. The lymphocytes become abnormal causing them to multiply too quickly and live for too long. Patients with CLL/SLL have too many abnormal lymphocytes circulating in the blood, causing the symptoms you may have. The disease can also affect other organs in your body.

ZYDELIG is used in combination with other medicines, for the treatment of CLL/SLL in patients whose disease has returned following a period of improvement.

ZYDELIG is also used to treat Follicular lymphoma

Follicular lymphoma (FL) is a cancer of the lymphatic system affecting a type of white blood cell called lymphocytes. The lymphocytes become abnormal causing them to multiply too quickly and live for too long and are involved in the cause of some of the symptoms you may have. ZYDELIG is a medicine that can be used for the

treatment of FL in patients whose disease no longer responds to other treatments.

Your doctor may have prescribed ZYDELIG for another reason.

2. What should I know before I use ZYDELIG?

Warnings

Do not use ZYDELIG if:

- you are allergic to idelalisib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have an active infection
- have lung or breathing problems
- have liver problems, including Hepatitis B or Hepatitis C. Your doctor may screen you for Hepatitis B or Hepatitis C infection before you start your treatment with ZYDELIG.

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

ZYDELIG is not recommended for use during pregnancy or breast-feeding.

There is no information about the safety of ZYDELIG in pregnant women.

Use a reliable method of contraception to avoid becoming pregnant while you're being treated with ZYDELIG and for 1 month after your last treatment.

Your doctor will discuss the potential benefits and risks of taking ZYDELIG to you and your child.

It is not known whether the ingredients in ZYDELIG pass into human milk.

If you are breast-feeding, talk to your doctor to discuss whether you should continue before starting treatment with ZYDELIG.

Immunisation and ZYDELIG

There is not enough information available about the use of immunisation with ZYDELIG.

Your doctor will determine if you are at substantial risk of an infection (eg, influenza or pneumococcal sepsis) that may be prevented by immunisation.

Your doctor may consider giving you the vaccine prior to treatment.

Progressive multifocal leukoencephalopathy (PML)

PML is a serious and life threatening brain condition. PML has been reported in some patients who have received immunotherapy.

Use in Children

- **Do not give this medicine to a child under the age of 18 years.**
- Safety and effectiveness in children younger than 18 years have 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 and ZYDELIG may interfere with each other. These include:

- carbamazepine, phenytoin (used to prevent seizures)
- rifampicin (used to prevent and treat tuberculosis and other infections)
- St. John's Wort (*Hypericum perforatum*, a herbal remedy used for depression and anxiety)
- alfentanil, fentanyl (used for pain relief)
- ciclosporin, sirolimus, tacrolimus (used to control your body's immune response after a transplant)
- dihydroergotamine, ergotamine (used to treat migraine headache)
- pimozide (used to treat illnesses affecting the way you think, feel or behave)
- quinidine (used to correct irregular heartbeats)

These medicines may be affected by ZYDELIG or may affect how well it works. 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 this medicine.

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

Do not start any new medicines while you are taking ZYDELIG without first talking with your doctor or pharmacist.

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

4. How do I use ZYDELIG?

How much to take

- The recommended dose for adults is 150 mg administered orally twice daily.
- Take the exact amount of ZYDELIG your doctor has prescribed for you. Never change the dose on your own. Your dose may be reduced by your doctor to 100 mg (taken orally twice daily) if you experience particular side effects.
- ZYDELIG can be taken with or without food.

When to take ZYDELIG

- Take your medicine at about the same time each day.
- Taking it at the same time each day will help you remember when to take it.

How to take ZYDELIG

- Swallow the tablet whole.
- Do not chew, crush or split the tablet.
- Tell your doctor if you have problems swallowing tablets.

How long to take ZYDELIG

- Continue taking your medicine for as long as your doctor tells you.
- It is important to keep taking your medicine even if you feel well.
- Do not stop this medicine unless your healthcare provider tells you to stop.

If you forget to use ZYDELIG

ZYDELIG should be used regularly at the same time each day.

If you miss a dose of ZYDELIG by less than 6 hours, take the missed dose right away. Then take your next dose as you would normally.

If you miss a dose of ZYDELIG by more than 6 hours, skip the dose you missed and take your next dose when you would normally.

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

Do not change your dose or stop taking ZYDELIG without first talking to your doctor.

If you use too much ZYDELIG

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or in New Zealand the Poisons Centre (telephone 0800 764 766)
- 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.

If you accidentally take more than the recommended dose of ZYDELIG you may be at increased risk of experiencing possible side effects with this medicine.

5. What should I know while using ZYDELIG?

Things you should do

Call your doctor straight away if you get any of the following symptoms during treatment with ZYDELIG:

Infection

- fever, severe chills, sore throat or mouth
- cough or flu-like symptoms
- blood in your phlegm
- muscle aches
- diarrhoea or stomach pain
- burning when you urinate or urinating more often than normal
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale

Severe Skin Reactions

- painful sores or ulcers on your skin, lips or in your mouth
- severe rash with blisters or peeling skin

Liver Problems

- yellowing of your skin or the white part of your eyes (jaundice)
- dark or brown (tea coloured) urine
- pain in the upper right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Blood tests may also show changes in your liver.

Before and during treatment with ZYDELIG, you will have regular blood tests to check for the proper functioning of your liver. Your doctor may decide to temporarily interrupt treatment to allow your liver to recover, before resuming treatment at the same or a lower dose.

Diarrhoea and Fever

ZYDELIG may increase the risk of diarrhoea and fever during treatment. Tell your doctor as soon as possible if you have these symptoms or you experience any changes in these symptoms.

Remind any doctor, dentist or pharmacist you visit that you are using ZYDELIG.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not breast-feed.
- Do not take ZYDELIG after the expiry or “use by” date (EXP) printed on the bottle. If you take it after the expiry date has passed, it may not work as well.
- Do not take ZYDELIG if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZYDELIG affects you.

You may feel tired after taking ZYDELIG, which may affect your ability to drive or use any tools or machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep ZYDELIG tablets in a cool, dry place where it stays below 30°C.
- Keep your ZYDELIG tablets in the bottle with the cap tightly closed until you take them. If you take ZYDELIG tablets out of their pack 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 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

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 which is stated on the bottle and carton after EXP.

The expiry date refers to the last day of that month.

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.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">diarrhoea/inflammation of the large intestinedecreased number of white blood cellsinfectionsrashfeverlung inflammationincreased blood levels of liver enzymes or fats <p>Allergic Reaction:</p> <p>Some of the symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none">coughshortness of breathwheezing or difficulty breathingswelling of the face, lips, tongue or other parts of the bodyrash, itching or hives on the skin.	<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>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effect you experience, you can report side effects in Australia to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems and in New Zealand online at <https://pophealth.my.site.com/carmreportnz/s/>. 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 ZYDELIG contains

Active ingredient (main ingredient)	idelalisib
Other ingredients (inactive ingredients)	microcrystalline cellulose hypromellose croscarmellose sodium sodium starch glycolate magnesium stearate Film-coating (150 mg): polyvinyl alcohol (E1203) macrogol 3350 (E1521) titanium dioxide (E171) talc (E553B) iron oxide red (E172) Film-coating (100 mg): Polyvinyl alcohol (E1203) macrogol 3350 (E1521) titanium dioxide (E171) talc (E553B) sunset yellow FCF aluminium lake (E110).
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What ZYDELIG looks like

ZYDELIG 150 mg film-coated tablets are pink, oval-shaped film-coated tablets, debossed on one side with "GSI" and "150" on the other side (AUST R 218839)

ZYDELIG 100 mg film-coated tablets are orange, oval-shaped film-coated tablets, debossed on one side with "GSI" and "100" on the other side (AUST R 218837).

ZYDELIG tablets are supplied in bottles containing 60 tablets.

Who distributes ZYDELIG

Australia

Gilead Sciences Pty Ltd

Level 28, 385 Bourke Street,

Melbourne, Victoria, 3000, Australia

New Zealand

c/o Tompkins Wake
Level 17, 88 Shortland Street,
Auckland, 1010

This leaflet was prepared in December 2025.

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