

Zydelig Tablets
100 mg and 150 mg tablets
(zi-del-ig)
Idelalisib

Consumer Medicine Information

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.

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

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

If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What is Zydelig used for

ZYDELIG contains the active substance idelalisib, 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.

Your doctor may prescribe ZYDELIG for the treatment of:

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.

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.

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

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.

Before you take Zydelig

When you must not take it

Together with your doctor, you need to decide whether ZYDELIG is right for you.

Do not take ZYDELIG if you have an allergy to:

- any medicine containing idelalisib
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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.

ZYDELIG may increase the risk of the following symptoms during treatment:

- diarrhoea
- fever

Tell your doctor as soon as possible if you have these symptoms or you experience any changes in these symptoms.

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.

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

Infection

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

- 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

Tell your doctor if you get any of the following symptoms during treatment with ZYDELIG:

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

Liver Problems

Tell your doctor right away if you get any of the following symptoms of 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.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medications, herbal supplements, or vitamins including any that you get 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.

How to take Zydelig

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

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.

How to take it

Swallow the tablet whole.

Do not chew, crush or split the tablet.

Tell your doctor if you have problems swallowing tablets.

When to take it

Take your medicine at about the same times each day.

Taking it at the same times each day will help you remember when to take it.

ZYDELIG can be taken with or without food.

How long to take it

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 take it

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 change your dose or stop taking ZYDELIG without first talking to your doctor.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 131126 (Australia) and 0800 764 766 (New Zealand) or go to the accident and emergency department at your nearest hospital, if you think you or anyone else may have taken too many ZYDELIG tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

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.

While you are taking Zydelig

Things you must not do

Do not breast-feed. See "Before you start to take it"

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.

Things to be careful of

Driving and using machines

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZYDELIG, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- diarrhoea/inflammation of the large intestine
- decreased number of white blood cells
- infections
- rash
- fever

The above list includes the more common side effects of your medicine (may affect at least 1 in every 10 patients treated).

Other side effects include:

- lung inflammation
- increased blood levels of liver enzymes or fats

Tell your doctor right away if you get new or worsening cough, shortening of breath, difficulty breathing, or wheezing.

Ask your doctor or pharmacist if you don't understand anything in this list.

This is not a complete list of side effects possible with ZYDELIG. Ask your doctor or pharmacist for a more complete list of side effects of ZYDELIG and all the medicines you will take.

After taking ZYDELIG

Storage

Keep ZYDELIG tablets where children cannot reach them.

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

Keep ZYDELIG tablets in a cool, dry place where it stays below 30°C.

Do not store ZYDELIG or any other medicine in a bathroom or near a sink.

Do not leave ZYDELIG in the car or on a window sill.

Heat and dampness can destroy some medicines.

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.

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.

Product description

What it 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.

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.

ZYDELIG tablets are supplied in bottles containing 60 tablets.

Ingredients

ZYDELIG 150 mg film-coated tablets contain 150 mg of idelalisib as the active ingredient.

It also contains:

- microcrystalline cellulose
- hypromellose
- croscarmellose sodium
- sodium starch glycolate
- magnesium stearate

Film-coating:

- polyvinyl alcohol (E1203)
- macrogol 3350 (E1521)
- titanium dioxide (E171)
- talc (E553B)
- iron oxide red (E172)

ZYDELIG 100 mg film-coated tablets contain 100 mg of idelalisib as the active ingredient.

It also contains:

- microcrystalline cellulose
- hyprolose
- croscarmellose sodium
- sodium starch glycolate
- magnesium stearate

Film-coating:

- Polyvinyl alcohol (E1203)
- macrogol 3350 (E1521)
- titanium dioxide (E171)
- talc (E553B)
- sunset yellow FCF aluminium lake (E110).

Sponsor

ZYDELIG is supplied in Australia by:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

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AUST R 218837 - 100 mg

AUST R 218839 - 150 mg

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