

Package leaflet: Information for the patient

Zydelig 100 mg film-coated tablets idelalisib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zydelig is and what it is used for
2. What you need to know before you take Zydelig
3. How to take Zydelig
4. Possible side effects
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1. What Zydelig is and what it is used for

Zydelig is a cancer medicine that contains the active substance idelalisib. It works by blocking the effects of an enzyme involved in multiplication and survival of certain white blood cells called lymphocytes. Because this enzyme is overactivated in certain cancerous white blood cells, by blocking it, Zydelig will kill and reduce the number of cancer cells.

Zydelig may be used for the treatment of two different cancers in adults:

Chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia (CLL) is a cancer of a type of white blood cell called B-lymphocytes. In this disease, the lymphocytes multiply too quickly and live for too long, so that there are too many of them circulating in the blood.

In CLL Zydelig treatment is used in combination with another medicine (rituximab) in patients who have certain high-risk factors or in patients whose cancer has come back after at least one previous treatment.

Follicular lymphoma

Follicular lymphoma (FL) is a cancer of a type of white blood cell called B-lymphocytes. In follicular lymphoma, the B-lymphocytes multiply too quickly and live for too long, so there are too many of them in the lymph nodes. In FL Zydelig is used on its own in patients whose cancer has not responded to treatment with two previous cancer treatments.

2. What you need to know before you take Zydelig

Do not take Zydelig

- if you are **allergic** to idelalisib or any of the other ingredients of this medicine (listed in section 6).
→ **Talk to your doctor** if this applies to you.

Warnings and precautions

Talk to your doctor before taking Zydelig. Tell your doctor:

- if you have liver problems
- if you have any other medical conditions or illness (especially an infection or fever)

Serious and fatal infections have occurred in patients taking Zydelig. You should take additional medicine provided by your doctor while you are taking Zydelig to prevent one type of infection. Your doctor will monitor you for evidence of infection. Tell your doctor right away if you become ill (especially with a fever, cough or breathing difficulties) while you are taking Zydelig.

Tell your doctor immediately if you notice or someone notices in you: memory loss, trouble thinking, difficulty walking or sight loss – these may be due to a very rare but serious brain infection which can be fatal (progressive multifocal leukoencephalopathy or PML).

You will need regular blood tests before and during treatment with Zydelig. This is to check that you do not have an infection, that your liver is working properly, and that your blood counts are normal. If necessary, your doctor may decide to stop treatment for a while, before starting treatment again at the same or a lower dose. Your doctor may also decide to permanently stop treatment with Zydelig.

Zydelig can cause severe diarrhoea. Tell your doctor right away at the first sign of diarrhoea.

Zydelig can cause lung inflammation. Tell your doctor right away:

- if you have a new or worsening cough
- if you have shortness of breath or difficulty breathing

Severe skin blistering conditions including Stevens-Johnson syndrome and toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with idelalisib treatment. Stop using idelalisib and seek medical attention immediately if you notice any of the symptoms described in section 4.

Tell your doctor right away:

- if you have redness and blistering of the skin
- if you have swelling and blistering of the lining of the mouth, throat, nose, genitals, and/or eyes

Laboratory tests may show an increase in white blood cells (called “lymphocytes”) in your blood in the first few weeks of treatment. This is expected and may last for a few months. This generally does not mean that your blood cancer is getting worse. Your doctor will check your blood counts before or during treatment with Zydelig and in rare cases they may need to give you another medicine. Talk to your doctor about what your test results mean.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Zydelig

Zydelig should not be used with any other medicines unless your doctor has told you it is safe to do so.

Tell your doctor if you are taking, have recently taken or might take any other medicines. This is extremely important, as using more than one medicine at the same time can strengthen or weaken their effect.

Taking Zydelig with certain medicines may stop them working properly, or may make side effects worse. In particular, tell your doctor if you are taking any of the following:

- **alfuzosin**, a medicine used to treat an enlarged prostate
- **dabigatran, warfarin**, medicines used to thin the blood

- **amiodarone, bepridil, disopyramide, lidocaine, quinidine**, medicines used to treat heart problems
- **dihydroergotamine, ergotamine**, medicines used to treat migraine headache
- **cisapride**, a medicine used to relieve certain stomach problems
- **pimozide**, a medicine used to treat abnormal thoughts or feelings
- **midazolam, triazolam**, when taken by mouth to help you sleep and/or relieve anxiety
- **quetiapine**, a medicine used to treat schizophrenia, bipolar disorder and major depressive disorder
- **amlodipine, diltiazem, felodipine, nifedipine, nifedipine**, medicines used to treat high blood pressure and heart problems
- **bosentan**, a medicine used to treat pulmonary arterial hypertension
- **sildenafil, tadalafil**, medicines used to treat impotence and pulmonary hypertension, a lung disease that makes breathing difficult
- **budesonide, fluticasone**, medicines used to treat hayfever and asthma, and **salmeterol**, used to treat asthma
- **rifabutin**, a medicine used to treat bacterial infections including tuberculosis
- **itraconazole, ketoconazole, posaconazole, voriconazole**, medicines used to treat fungal infections
- **boceprevir, telaprevir**, medicines used to treat hepatitis C
- **carbamazepine, S-mephenytoin, phenytoin**, medicines used to prevent seizures
- **rifampicin**, a medicine 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, methadone, buprenorphine/naloxone**, medicines used for pain relief
- **ciclosporin, sirolimus, tacrolimus**, medicines used to control your body's immune response after a transplant
- **colchicine**, a medicine used to treat gout
- **trazodone**, a medicine used to treat depression
- **bupirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem**, medicines used to treat nervous system disorders
- **dasatinib, nilotinib, paclitaxel, vinblastine, vincristine**, medicines used to treat cancer
- **oral or implanted hormonal contraceptives**, used to prevent pregnancy
- **clarithromycin, telithromycin**, medicines used to treat bacterial infections
- **atorvastatin, lovastatin, simvastatin**, medicines used to lower cholesterol

Zydelig may be prescribed in combination with other medicines for the treatment of CLL. It is very important that you read the package leaflets that are provided with these medicines too.

Ask your doctor if you have any questions about any of your medicines.

Pregnancy and breast-feeding

- **Zydelig should not be used during pregnancy.** There is no information about the safety of this medicine in pregnant women.
- **Use a reliable method of contraception** to avoid becoming pregnant while you are being treated with Zydelig, and for 1 month after your last treatment.
- **Zydelig may make the contraceptive “pill” and implanted hormonal contraceptives work less well.** You must also use a barrier method of contraception such as condoms or the “coil” while taking Zydelig and for 1 month after your last treatment.
- **Tell your doctor immediately if you become pregnant.**

You should not breast-feed while taking Zydelig. If you are currently breast-feeding, talk to your doctor before starting treatment. It is not known whether the active substance in Zydelig passes into human milk.

Driving and using machines

Zydelig is unlikely to affect your ability to drive or use machines.

Zydelig contains sunset yellow FCF (E110)

Tell your doctor if you have an allergy to sunset yellow FCF (E110). Zydelig contains sunset yellow FCF which may cause allergic reactions.

Zydelig contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zydelig

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is 150 mg by mouth twice a day. However, your doctor may reduce this dose to 100 mg twice a day if you experience particular side effects.

Zydelig can be taken with or without food.

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

If you take more Zydelig than you should

If you accidentally take more than the recommended dose of Zydelig, you may be at increased risk of side effects with this medicine (see section 4, *Possible side effects*).

Contact your doctor or nearest emergency department immediately for advice. Keep the bottle and this leaflet with you so that you can easily describe what you have taken.

If you forget to take Zydelig

Take care to not miss a dose of Zydelig. If you miss a dose by less than 6 hours, take the missed dose right away. Then take your next dose as usual. If you miss a dose by more than 6 hours, wait and take the next dose at your usual time.

Do not stop taking Zydelig

Do not stop taking this medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious.

STOP taking Zydelig and seek medical help immediately if you experience any of the following:

- Reddish patches on the trunk, small circumscribed changes in the colour of the skin, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis) (*a rare side effect – may affect up to 1 in 1 000 people*)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome) (*the frequency of this side effect is not known*)

Other side effects

Very common side effects

(may affect more than 1 in 10 people)

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

Blood tests may also show:

- increased blood levels of liver enzymes
- increased blood levels of fats

Common side effects

(may affect up to 1 in 10 people)

- inflammation of the lungs
- liver damage

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the *Yellow Card Scheme, Website:*

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zydelig

Keep this medicine out of the sight and reach of children.

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.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zydelig contains

- **The active substance is** idelalisib. Each film-coated tablet contains 100 mg of idelalisib.

- **The other ingredients are:**

Tablet core:

Microcrystalline cellulose, hydroxypropyl cellulose (E463), croscarmellose sodium, sodium starch glycolate, magnesium stearate.

Film-coating:

Poly (vinyl alcohol) (E1203), macrogol (E1521), titanium dioxide (E171), talc (E553B), sunset yellow FCF (E110) (see Section 2, *What you need to know before you take Zydelig*).

What Zydelig looks like and contents of the pack

Zydelig 100 mg film-coated tablets are orange, oval-shaped tablets, debossed on one side with “GSI” and “100” on the other side.

The following pack size is available: outer carton containing 1 plastic bottle of 60 film-coated tablets.

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