

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

5. How to store Zydelig

6. Contents of the pack and other information

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:

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 is used in combination with another medicine called 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

You will need regular blood tests before and during treatment with Zydelig. This is to check that your liver is working properly. If necessary, your doctor may decide to stop treatment for a while to allow your liver to recover, before starting treatment again at the same or a lower dose.

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

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, rivaroxaban, 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**, 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

- **buspirone, 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 breastfeeding

- **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 breastfeed while taking Zydelig. If you are currently breastfeeding, 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.

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.

Very common side effects

(may affect more than 1 in 10 people)

- diarrhoea/inflammation of the large intestine

- rash

- decreased number of white blood cells

- infections

- fever

Common side effects

(may affect up to 1 in 10 people)

- inflammation of the lungs

Blood tests may also show:

- increased blood levels of liver enzymes or fats

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 national reporting system.

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.

Store below 30°C.

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:

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

What Zydelig looks like and contents of the pack

The 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.

Marketing Authorisation Holder and Manufacturer

Gilead Sciences International Ltd
Cambridge
CB21 6GT
United Kingdom

Manufacturer:
Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

This leaflet was last revised in MM/YYYY.

To report any side effect(s):

Please contact the relevant competent authority

THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions for the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.

Council of Arab Health Ministers and Union of Arab Pharmacists

EUSEP14LBJAN15

