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# Zydelig (*idelalisib*)

An overview of Zydelig and why it is authorised in the EU

## What is Zydelig and what is it used for?

Zydelig is a cancer medicine that is used to treat chronic lymphocytic leukaemia (CLL, a cancer of a type of white blood cells called B lymphocytes) and follicular lymphoma (another cancer that affects B lymphocytes).

In CLL, Zydelig is used in combination with another medicine (rituximab or ofatumumab) in patients who have received at least one previous treatment and in patients whose cancer cells have genetic mutations (changes) called 17p deletion or *TP53* mutation and who cannot be treated with any other therapy.

In follicular lymphoma, Zydelig is used on its own in patients whose disease has not improved with two previous treatments.

Zydelig contains the active substance idelalisib.

## How is Zydelig used?

Zydelig can only be obtained with a prescription and it should be prescribed by a doctor experienced in using cancer medicines.

Zydelig is available as 100 mg and 150 mg tablets. The recommended dose is 150 mg twice a day, and treatment should be continued for as long as the patient improves or remains stable and the side effects are tolerable. If the patient has severe side effects, treatment must be stopped and can be re-started at a lower dose of 100 mg twice a day.

All patients treated with Zydelig should also be given preventive medication against the lung infection *Pneumocystis jirovecii* pneumonia, and this should be continued for up to 6 months after stopping treatment with Zydelig. Patients should also be monitored for infection and have regular blood tests to measure the level of white blood cells. Zydelig should not be started in patients with any generalised infection (infection that has spread with symptoms affecting the whole body, such as fever and chills).

For more information about using Zydelig, see the package leaflet or contact your doctor or pharmacist.

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## How does Zydelig work?

The active substance in Zydelig, idelalisib, blocks the effects of an enzyme called PI3K-delta. This enzyme plays a role in the growth, migration and survival of white blood cells but is overactive in blood cancers, where it enables the survival of the cancer cells. By targeting this enzyme and blocking its effects, idelalisib causes death of the cancer cells, thereby delaying or stopping the progression of the cancer.

## What benefits of Zydelig have been shown in studies?

In a main study of 220 patients with previously treated CLL, Zydelig was more effective at treating the cancer than placebo (a dummy treatment) when both were given in combination with rituximab: 75% of patients taking Zydelig had an improvement in their disease compared with 15% of patients receiving placebo. Zydelig was also more effective than placebo in patients who had a specific genetic mutation in their cancer cells that makes them unsuitable for certain other therapies.

Zydelig with ofatumumab was more effective than ofatumumab alone in the treatment of CLL. In a study of 261 previously treated CLL patients, it took over 16 months on average before the disease got worse in patients treated with Zydelig plus ofatumumab, compared with 8 months in those treated with ofatumumab alone.

Another main study evaluated Zydelig in patients with different lymphomas, including 72 patients with follicular lymphoma that had failed two previous treatments. Zydelig was effective, with 54% of patients with follicular lymphoma having either a complete or partial response to treatment.

## What are the risks associated with Zydelig?

The most common side effects with Zydelig (which may affect more than 1 in 10 people) are infections (including lung infection caused by *Pneumocystis jirovecii,* and cytomegalovirus infections), neutropenia (low levels of neutrophils, a type of white blood cell), lymphocytosis (increased levels of lymphocytes, another type of white blood cell), diarrhoea, blood tests showing changes in the liver, rash, fever and increased blood fat levels.

For the full list of side effects and restrictions of Zydelig, see the package leaflet.

## Why is Zydelig authorised in the EU?

The European Medicines Agency noted that data from the main studies showed high response rates with Zydelig in patients with chronic lymphocytic leukaemia and follicular lymphoma. Zydelig was also effective in chronic lymphocytic leukaemia patients whose cancer cells have the 17p deletion or TP53 mutation, who usually have a poor outcome.

In addition, the safety of the medicine was considered acceptable. The Agency therefore concluded that Zydelig's benefits are greater than its risks and recommended that it be approved for use in the EU.

## What measures are being taken to ensure the safe and effective use of Zydelig?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zydelig have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zydelig are continuously monitored. Side effects reported with Zydelig are carefully evaluated and any necessary action taken to protect patients.

## Other information about Zydelig

Zydelig received a marketing authorisation valid throughout the EU on 18 September 2014.

Further information on Zydelig can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zydelig.

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