EMA/674495/2017
EMEA/H/C/003843

EPAR summary for the public

Zydelig

idelalisib

This is a summary of the European public assessment report (EPAR) for Zydelig. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zydelig.

For practical information about using Zydelig, patients should read the package leaflet or contact their doctor or pharmacist.

What is Zydelig and what is it used for?

Zydelig is a cancer medicine that is used to treat two types of blood cancer: chronic lymphocytic leukaemia (CLL, a cancer of a type of white blood cells called B lymphocytes) and follicular lymphoma (one of another group of cancers that affect 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 who have genetic mutations in their cancer cells called 17p deletion or *TP53* mutation who cannot be treated with any other therapy.

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

Zydelig contains the active substance idelalisib.

How is Zydelig used?

Zydelig can only be obtained with a prescription and treatment 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 experiences severe side effects, treatment must be stopped and can be re-started at a lower dose of 100 mg twice a day.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

All patients treated with Zydelig should be given preventive medication against the lung infection *Pneumocystis jirovecii* pneumonia during treatment, and this should be continued for up to 6 months after treatment with Zydelig has stopped. Patients receiving Zydelig should also be monitored for signs of 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.

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 shown to be 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 taking placebo. Zydelig was also more effective than placebo in the subgroup of patients who had a specific genetic mutation in their cancer cells that makes them unsuitable for certain other therapies.

Zydelig with ofatumumab was also shown to be 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 started getting 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 shown to be 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, increased liver enzymes in blood, rash, fever and increased blood fat levels. For the full list of all side effects reported with Zydelig, see the package leaflet.

Based on studies in animals, Zydelig may be harmful to the unborn child. Zydelig is therefore not recommended during pregnancy, and women taking the medicine should use a reliable method of contraception to avoid becoming pregnant during treatment and for 1 month after treatment. It is also not known whether Zydelig can make hormonal contraceptives less effective. Women and their partners should therefore also use a barrier method of contraception such as condoms.

For the full list of restrictions, see the package leaflet.

Why is Zydelig approved?

The European Medicines Agency noted that available data from the main studies, two of which were still ongoing at the time of the evaluation, 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?

The company that markets Zydelig will provide final results of the ongoing main studies in patients with chronic lymphocytic leukaemia and follicular lymphoma.

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

Other information about Zydelig

The European Commission granted a marketing authorisation valid throughout the European Union for Zydelig on 18 September 2014.

The full EPAR for Zydelig can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Zydelig, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.