

## Idelalisib

This information is about idelalisib, a targeted drug used in the treatment of certain types of lymphoma.

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## What is idelalisib?

Many newer [treatments for lymphoma](#) are [targeted drugs](#).

Targeted drugs aim to kill the type of cell that has turned [cancerous](#) or stop signals that make cancerous cells grow or divide. In lymphoma, the type of cell that becomes cancerous is called a 'lymphocyte' (a type of white blood cell that fights infection). There are several types of lymphocyte, such as B lymphocytes (B cells) and T lymphocytes (T cells), which can be targeted by these newer treatments.

Cells receive signals that keep them alive and make them divide. These signals are sent along one or more signalling pathways inside the body. Idelalisib (Zydelig®) is a [cell signal blocker](#). It targets a protein called 'phosphatidylinositol 3-kinase' (PI3K), which is one of the steps in a pathway that helps B cells to stay alive and divide. This pathway is particularly important in helping cancerous B cells (lymphoma cells) stay alive when they should have died. Blocking the PI3K pathway with idelalisib can stop lymphoma cells dividing or cause them to die, stopping the spread of the lymphoma.

Idelalisib was previously known as GS-1101 or CAL-101.

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## Who can have it?

At the time of writing, idelalisib is **approved in Europe** for the following types of lymphoma.

### Chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL)

- For people who have had previous treatment for CLL/SLL. Idelalisib is given with **rituximab** or **ofatumumab** (both **antibody treatments**).
- For people with genetic changes in their cells that make their CLL/SLL harder to treat (called '17p deletion', where some genes are missing) and who are unable to have other treatments, such as **chemotherapy**. Idelalisib is given with rituximab or ofatumumab.

### Follicular lymphoma

- For people whose follicular lymphoma is refractory (not responding to treatment) after at least two previous treatments. Idelalisib is given on its own.

Idelalisib is also being tested in clinical trials for various types of lymphoma. Visit our clinical trials information service, **Lymphoma TrialsLink** to find out more about clinical trials and to search our database for a clinical trial that might be suitable for you.

## Is it available on the NHS in the UK?

Idelalisib has been **assessed by health authorities** for some uses on the NHS in the UK. It is currently only available on the NHS for some people in certain parts of the UK.

### In Scotland

- Idelalisib can be used in combination with rituximab for people who have had previous treatment for CLL/SLL and who are not able to have chemotherapy.
- Idelalisib can be used as a first-line treatment in combination with rituximab for people with genetic changes in their cells that make their CLL/SLL harder to treat (17p deletion, where some genes are missing).
- Idelalisib can be used for people who have had at least two previous courses of treatment for follicular lymphoma.

### In England and Wales

- Idelalisib can be used in combination with rituximab for people who have had previous treatment for CLL/SLL but whose CLL/SLL has got worse within 2 years of their previous treatment.

- Idelalisib can be used for people with CLL/SLL who have genetic changes in their cells that make their condition harder to treat (17p deletion, where some genes are missing) and who are unable to have other treatments.
- Idelalisib is not available on the NHS for people with follicular lymphoma.

Northern Ireland usually follows National Institute for Health and Care Excellence (NICE) recommendations, which cover England and Wales.

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## Benefits

### Benefits in CLL/SLL

Idelalisib was shown to be very effective at treating CLL/SLL in a clinical trial of 220 people who had previously received treatment. This trial compared idelalisib in combination with rituximab with placebo (a dummy treatment instead of idelalisib) in combination with rituximab. Three in four people treated with idelalisib and rituximab responded to treatment (their CLL/SLL improved). Only around one in every seven people treated with placebo (a dummy treatment) and rituximab responded to treatment. Some of the people in this trial had genetic changes that make their CLL more difficult to treat, and these people also responded better to idelalisib and rituximab than to placebo and rituximab.

Idelalisib is also effective in treating CLL in combination with another antibody treatment, called ofatumumab. In a study of 261 people who had received previous treatment for their CLL, the disease stayed under control for twice as long in people who had idelalisib with ofatumumab compared with those who had ofatumumab alone.

### Benefits in follicular lymphoma

Around half of people who had at least two previous courses of treatment for follicular lymphoma responded to idelalisib in a trial that included 72 people with follicular lymphoma.

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## How is it given?

Idelalisib is taken as tablets. Always follow the advice of your doctor when taking idelalisib. You can usually take the treatment at home.

You take idelalisib twice a day.

You take idelalisib every day until your lymphoma stops responding to it, unless side effects are bad enough to make you stop treatment. You might be treated with idelalisib for years.

Keep taking idelalisib for as long as your doctor tells you to, even if you feel well. If idelalisib is keeping your lymphoma under control, the lymphoma could get worse if you stop taking the drug.

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## Possible side effects

All medicines can cause **side effects** (unwanted effects of treatment).

Only the most common side effects of idelalisib are described on this page. This is not a complete list of side effects that have been reported. As idelalisib is a new treatment, more information about possible side effects is still being gathered. There is limited information about **late effects** (side effects that only develop months or years after treatment has finished) of idelalisib. Your medical team should discuss the most up-to-date information about side effects with you before you start treatment. Ask all the questions you have.

**Tell your medical team about any other medical conditions you have, as you might need additional monitoring or changes to the management of other conditions if you are treated with idelalisib. You must also tell your medical team about any medicines, supplements or complementary therapies you are taking before you start any new treatment.**

Most side effects experienced by people treated with idelalisib are mild. Tell your medical team if you notice any changes in your health. You might need to take a lower dose of idelalisib or stop treatment temporarily if you are having troublesome side effects, or you might need other treatments to help with side effects.

### **Most common side effects (occur in more than 1 in 10 people):**

- increased risk of infections, including serious infections like pneumonia, cytomegalovirus and fungal infections
- **neutropenia** (low neutrophils, a type of white blood cell that fights infection)
- lymphocytosis (increased levels of lymphocytes – this does not normally cause any problems)
- **diarrhoea**
- rash
- fever
- increased blood fat levels, and increased liver enzymes in blood tests (which can indicate problems with your liver).

### **Less common but possibly serious side effects:**

- pneumonitis (inflammation of the lungs)
- colitis (inflammation of the large intestine)
- Stevens-Johnson syndrome or Toxic Epidermal Necrolysis (serious skin disorders).

Some people treated with idelalisib have developed colitis months after treatment started. Tell your doctor if you experience any new or worsening diarrhoea. If you develop colitis, your idelalisib treatment might be stopped temporarily and treatments given to help your symptoms, such as anti-inflammatory drugs.

Several **clinical trials** with idelalisib were stopped because of people getting serious infections. This was more likely to happen when idelalisib was used together with other drugs. However, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) concluded after review that the benefits of idelalisib outweighed the risk of side effects in CLL and follicular lymphoma. Measures have been put in place to reduce the risk of infection. If you are taking idelalisib, your doctor monitors you for infection. You will also be given antibiotics during and after treatment to prevent a serious infection developing.

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## **Precautions**

You might need to take certain precautions while being treated with idelalisib.

Lots of medications, including herbal remedies, can interact with idelalisib and should not be taken with it. They could increase the risk of side effects or change the effect of idelalisib. Give your doctor a list of all the medications you are taking. Make sure you include any vitamins, supplements or herbal remedies. Tell your doctor if you are considering starting any new medications before you start.

**Drugs that affect an enzyme called CYP3A4:** CYP3A4 acts on many drugs to help remove them from the body, including idelalisib. If you are taking a drug that interferes with the action of CYP3A4, it can decrease or increase the action of idelalisib, depending on how the drugs work together. It is important that your doctor knows about all the medications you are taking as there is a range of drugs that can affect idelalisib.

**Report any side effects to your doctor as soon as possible. Your doctor might be able to give you medicine or advice to help with troublesome side effects.**

Idelalisib has not been approved for use in people under 18.

Idelalisib could damage an unborn baby or be passed to your baby in breast milk. Below are some recommendations you should follow.

- Prevent getting pregnant during treatment and for at least 1 month afterwards.
- Use a barrier method of contraception, like condoms. The effect of idelalisib on hormonal contraceptives, for example the pill, is unknown.
- Do not breastfeed if you are taking idelalisib.

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We have separate information about the topics in **bold font**. Please get in touch if you'd like to request copies or if you would like further information about any aspect of lymphoma. Phone 0808 808 5555 or email [information@lymphoma-action.org.uk](mailto:information@lymphoma-action.org.uk).

## References

The full list of references is available on request. Please email [publications@lymphoma-action.org.uk](mailto:publications@lymphoma-action.org.uk) or call 01296 619409 if you would like a copy.

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