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Calquence (*acalabrutinib*)

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

What is Calquence and what is it used for?

Calquence is a cancer medicine used to treat adults with chronic lymphocytic leukaemia (CLL), a blood cancer affecting B cells (a type of white blood cell).

Calquence is used on its own (monotherapy) in patients with CLL who have had previous treatment. In patients who have not had previous treatment for the condition, Calquence may be used on its own or combined with another cancer medicine, obinutuzumab.

Calquence contains the active substance acalabrutinib.

How is Calquence used?

Calquence can only be obtained with a prescription and treatment should be started and supervised by a doctor with experience in the use of cancer medicines. It is available as capsules to be taken by mouth; the recommended dose is 100 mg taken twice a day. Calquence is continued as long as the cancer remains under control and there are no unacceptable side effects. Treatment may be interrupted or stopped, or the dose modified, if serious side effects occur or certain other medicines have to be taken.

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

How does Calquence work?

The active substance in Calquence, acalabrutinib, blocks an enzyme called Bruton's tyrosine kinase, which helps B cells to survive and grow. By blocking this enzyme, acalabrutinib is expected to slow down the build-up of cancerous B cells in CLL, thereby delaying progression of the cancer.

What benefits of Calquence have been shown in studies?

Two main studies have shown that Calquence is effective at delaying death or the worsening of the disease.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

One of the studies, involving 535 patients who had not had previous treatment for CLL, compared Calquence or its combination with obinutuzumab versus a combination of obinutuzumab with another cancer medicine, chlorambucil. After around 28 months, 8% of the patients given Calquence in combination and 15% given Calquence alone had died or their cancer had got worse, compared with 53% given obinutuzumab and chlorambucil.

A second main study involving 310 patients compared Calquence alone with a combination of other cancer medicines (rituximab and either idelalisib or bendamustine) in patients whose CLL had come back or not responded with previous treatment. After around 16 months, 17% of the patients given Calquence had died or their cancer had got worse, compared with 44% of those given the rituximab combinations.

What are the risks associated with Calquence?

The most common side effects with Calquence (which may affect more than 1 in 5 people) are infections, headache, diarrhoea, bruising, muscle pain, nausea (feeling sick), tiredness, cough and rash. When used in combination with other cancer medicines, joint pain, dizziness and constipation were also very common.

The most common serious reactions with Calquence (which may affect more than 1 in 20 people) were infections and low white and red blood cell counts (leucopenia, neutropenia, and anaemia).

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

Why is Calquence authorised in the EU?

The European Medicines Agency decided that Calquence's benefits are greater than its risks and it can be authorised for use in the EU. Clear benefit has been shown with Calquence in patients with CLL, either alone or, in patients who had not been previously treated, also with obinutuzumab. These results were considered clinically relevant, and although the studies involved older patients and patients with other illnesses the results are likely to apply to younger and fitter patients as well. The medicine's side effects are considered acceptable and in line with those of other medicines that work in the same way.

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

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

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

Other information about Calquence

Calquence received a marketing authorisation valid throughout the EU on 5 November 2020.

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

This overview was last updated in 11-2020.