EMA/124979/2025
EMEA/H/C/005299

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 in adults to treat:

- 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, Calquence may be used on its own or combined with another cancer medicine, obinutuzumab;
- mantle cell lymphoma (MCL; a blood cancer affecting B cells). Calquence is used on its own in patients whose MCL has come back (relapsed) or not responded (refractory) to treatment and who have not received treatment with a type of cancer medicine called a Bruton's tyrosine kinase (BTK) inhibitor. It is also used in combination with other cancer medicines, bendamustine and rituximab, in adults with previously untreated MCL who cannot have an autologous stem cell transplantation (ASCT). An ASCT is a procedure where the patient's bone marrow is replaced by their own stem cells to form new bone marrow that produces healthy cells.

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.

Calquence is available as capsules to be taken by mouth twice a day. Treatment can continue for as long as the patient benefits from it. However, if the patient develops severe side effects, the doctor may need to adjust the dose, pause or stop treatment permanently.

Calquence should not be used together with some medicines known as strong CYP3A inhibitors (such as certain antibiotics or medicines for fungal infections) or strong CYP3A inducers (such as certain medicines for epilepsy), as they may affect the way Calquence works in the body.

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

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

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 and MCL, thereby delaying progression of the cancer.

What benefits of Calquence have been shown in studies?

Chronic lymphocytic leukaemia

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

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

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

Mantle cell lymphoma

In a study involving 124 adults with MCL that had come back or not responded to previous treatment, and who had not received treatment with a BTK inhibitor, around 82% of patients (101 out of 124) responded to treatment with Calquence. These patients lived for an average of 29 months without their disease getting worse. The study did not compare Calquence with another medicine or placebo (a dummy treatment).

A second study, involving 598 adults aged 65 years and older with previously untreated MCL, showed that Calquence given in combination with bendamustine and rituximab is more effective than placebo with bendamustine and rituximab at delaying death or worsening of the cancer. Patients given Calquence lived on average for 66.4 months without their cancer getting worse compared with 49.6 months for patients given placebo.

What are the risks associated with Calquence?

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

The most common side effects with Calquence (which may affect more than 1 in 5 people) include infections, headache, diarrhoea, bruising, musculoskeletal pain (pain in the muscles and bones), nausea (feeling sick), tiredness, cough, joint pain and rash.

When Calquence is used in combination with obinutuzumab the most common side effects (which may affect more than 1 in 5 people) include infections, musculoskeletal pain, diarrhoea, headache, leucopenia (low levels of white blood cells), neutropenia (low levels of neutrophils, a type of white blood cell), cough, tiredness, joint pain, nausea, dizziness and constipation.

When Calquence is used in combination with bendamustine and rituximab, the most common side effects (which may affect more than 1 in 5 people) include neutropenia, nausea, rash, diarrhoea,

musculoskeletal pain, headache, tiredness, vomiting, constipation, anaemia (low levels of red blood cells) and thrombocytopenia (low levels of blood platelets, components that help the blood to clot).

Why is Calquence authorised in the EU?

Calquence showed clear benefits in patients with CLL, whether used on its own or in combination with obinutuzumab, in patients who had not received previous treatment. These results were considered clinically relevant. Even though the studies involved older patients and those with other illnesses, the results are likely to apply to younger and fitter patients too.

Most patients with previously untreated MCL who are older than 65 years are not able to undergo intensive treatments that are part of ASCT. Furthermore, there is an unmet medical need for patients with previously untreated MCL as there is no curative treatment available. The use of Calquence with bendamustine and rituximab delayed death or worsening of the cancer, that was considered to be valuable for patients.

Patients with MCL whose disease has come back or not responded to treatment with first-line therapy (the first treatment given for a disease) have poor outcomes and limited treatment options. The response rate to treatment with Calquence was found to be high and those who received the medicine had a durable response. However, there were some uncertainties due to the lack of comparator in the main study.

Calquence's side effects are considered acceptable and in line with those of other medicines that work in the same way.

The European Medicines Agency therefore decided that Calquence's benefits are greater than its risks and it can be authorised for use in the EU.

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 04-2025.