swissmedic

Summary report on authorisation dated 15 January 2026

Calquence® (active substance: acalabrutinib)

Indication extension in Switzerland: 7 October 2025

Film-coated tablets for the treatment of adults with previously untreated chronic lymphatic leukaemia (CLL) in combination with venetoclax.

About the medicinal product

Calquence is a medicinal product containing the active substance acalabrutinib.

Calquence (hard capsules) was first authorised by Swissmedic on 4 March 2021 for the treatment of chronic lymphatic leukaemia (CLL). The medicinal product has since been authorised for other indications.

This indication extension means that Calquence can be used in combination with venetoclax for the treatment of adults with chronic lymphatic leukaemia (CLL) who have not previously received any treatment for their disease.

CLL is a blood cancer that affects the lymphocytes (white blood cells) and the lymph nodes.

Mode of action

Calquence works by specifically blocking Bruton's tyrosine kinase. Bruton's tyrosine kinase is an enzyme[1] that is partly responsible for the survival and growth of cancer cells. By blocking this enzyme, Calquence can reduce the number of cancer cells and slow the progression of the disease.

Administration

Calquence is a prescription-only medicine and is authorised as film-coated tablets at the dosage strength of 100 mg.

The recommended dose is 1 film-coated tablet twice daily. Calquence should always be taken at the same time morning and evening, 12 hours apart. Calquence can be taken with or without food, and the film-coated tablets should be swallowed whole with water.

Treatment with Calquence in combination with venetoclax should be continued until the disease progresses, unacceptable side effects occur, or a maximum of 14 treatment

1 Enzymes: enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

cycles (of 28 days each) have been completed.

Efficacy

The efficacy of Calquence in combination with venetoclax was investigated in the AMPLIFY study. This involved patients aged 18 years and older with previously untreated chronic lymphatic leukaemia (CLL). The subjects were allocated at random to 1 of 2 treatment groups: One group received a combination of Calquence and venetoclax while the other received 1 of 2 possible chemoimmunotherapies chosen by the investigator. The results showed that the combination of Calquence and venetoclax delayed disease progression. The risk of disease progression or death was reduced by 35% compared to chemoimmunotherapy.

Precautions, undesirable effects, & risks

Calquence may not be used in those who are hypersensitive to the active substance or any of the excipients.

Frequent undesirable effects (affecting more than 1 in 10 users) include upper respiratory tract infections, pneumonia, headache, diarrhoea, musculoskeletal pain, joint pain, nausea, fatigue, rash, constipation, dizziness, vomiting, abdominal pain, bruises/bleeding, exhaustion, cough, and high blood pressure. A decrease in certain blood components, such as white blood cells, red blood cells, and platelets, also occurs frequently.

Calquence can also increase the risk of bleeding, particularly in patients who are already taking blood-thinning medications.

Other infectious risks include reactivation of a liver infection (hepatitis B).

An irregular heartbeat (atrial fibrillation) can also occur and should be monitored by a doctor.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The clinical study showed that the combination of Calquence and venetoclax can slow disease progression.

Chronic lymphatic leukaemia (CLL) continues to be incurable and there is a considerable medical need for safe and effective treatment options.

Taking all the risks and precautions into account, and based on the available data, the benefits of Calquence outweigh the risks. Swissmedic has therefore authorised Calquence, containing the active substance acalabrutinib, in combination with venetoclax in Switzerland for the treatment of adult patients with previously untreated CLL.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Calquence ®

Information for patients (package leaflet): Information for patients Calquence®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.