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Calquence® (active substance: acalabrutinib)

First authorisation in Switzerland: 4 March 2021

Medicinal product (hard capsule) for the treatment of chronic lymphocytic leukaemia (CLL)

About the medicinal product

Calquence is a cancer treatment containing the active substance acalabrutinib.

Treatment with Calquence is used to treat one of the following illnesses with chronic lymphocytic leukaemia (CLL):

1. Previously untreated CLL in adult patients aged 65 and older or who have concomitant illnesses. In this case, Calquence can either be used on its own or in combination with the active substance obinutuzumab.
2. CLL in adult patients who have received at least one previous treatment. In this case, Calquence is used as monotherapy (i.e. as the only medication).

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

Since this is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Mode of action

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

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

Use

Calquence is a prescription-only medicine authorised as a hard capsule at the dosage strength of 100 mg.

The recommended dose is 1 hard capsule twice daily. Calquence should always be taken at the same time every morning and evening 12 hours apart.

The capsules must be swallowed whole with a glass of water, either with or without food. The capsules must not be opened, dissolved or chewed before swallowing.

Efficacy

The efficacy of Calquence was evaluated in studies ACE_CL-007 (ELEVATE-TN) and ACE-C-309 (ASCEND).

The ELEVATE-TN study was conducted with CLL patients who had not previously received any treatment, whereas the ASCEND study enrolled patients with CLL who had already received at least one prior treatment.

1. Patients with previously untreated CLL

In the ELEVATE-TN study, 535 patients received differing treatments in 3 groups of almost equal size: 179 patients received the drug Calquence in combination with obinutuzumab, while a further 179 patients were treated with Calquence on its own. The remaining 177 patients received the comparison treatment of chlorambucil in combination with obinutuzumab. The median[2] treatment period was 28 months in both groups treated with Calquence and 5.5 months in those patients who received chlorambucil in combination with obinutuzumab. The median[2] follow-up period was 28 months.
The main aim of the study, to produce a significant improvement in PFS[3] compared to the comparison treatment, was achieved in both groups treated with Calquence (in combination with obinutuzumab or on its own). An improved response compared to the treatment with the comparator drug was shown only for the treatment of Calquence in combination with obinutuzumab. A prolongation of survival could not be assessed at the time of evaluation.

2. Patients with CLL who had received at least one prior treatment

310 patients in the ASCEND study either received Calquence on its own or received a comparison treatment (idelalisib and rituximab, or bendamustine and rituximab).

Of those patients who were treated with the drug Calquence for 16 months, disease progression was observed in 17.4% (27 of the 155 patients). By comparison, in those patients who received the comparison treatment for the same period, disease progression occurred in 43.9% (68 of 155 patients).

The main aim of the treatment with Calquence, to produce a significant improvement in progression-free survival (PFS)[3] compared to the comparison treatment, was achieved. Overall, the response and survival were comparable for both treatments.

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

[3] Progression-free survival (PFS): period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Precautions, undesirable effects & risks

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

Calquence may cause side effects, which must be reported to the doctor without delay.
The most commonly reported adverse reactions in patients treated with Calquence are headache, diarrhoea, upper respiratory infection, bruising, nausea, exhaustion or fatigue and cough.

Other serious side effects occurred during the administration of Calquence – e.g. bleeding, infections, anaemia and a reduction in other blood cells (regular blood tests are recommended), occurrence of other cancers (including skin cancer) and fast, irregular heartbeat.

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 medicine has been authorised

In both of the clinical trials investigating efficacy, a prolongation of PFS[3] was demonstrated for the treatment with Calquence.

Since CLL is a cancer that typically lasts for a long time, the final reports from these clinical trials should provide further information in future about the efficacy and safety of Calquence.

Based on all the available data, the benefits of Calquence outweigh the risks. Swissmedic has therefore authorised the medicinal product Calquence with the active substance acalabrutinib for the treatment of previously untreated CLL patients aged 65 and older or who have concomitant illnesses. In this case, Calquence can either be used on its own or in combination with the active substance obinutuzumab. Calquence has also been authorised as monotherapy for the treatment of adults with CLL who have received at least one prior therapy.

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 (doctors, pharmacists and others) 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 Public Summary SwissPAR.

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