swissmedic

Summary report on authorisation dated 23 September 2025

Scemblix® (active substance: asciminib)

Indication extension in Switzerland: 12 May 2025

Film-coated tablets for the treatment of adults with chronic-phase Philadelphia chromosome-positive chronic myeloid leukaemia with a T315I mutation

About the medicinal product

Scemblix contains the active substance asciminib, which is used for the treatment of adults with chronic-phase (CP) Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML).

Ph+ CML is a type of blood cancer in which the body produces excessive amounts of abnormal white blood cells. The CP is the early stage of CML. During this phase of the disease, most cancer cells have yet to proliferate or multiply aggressively.

Swissmedic first authorised Scemblix on 9 June 2022 for adults with Ph+ CML when two or more previous treatments with other medicinal products did not result in the desired treatment response or were poorly tolerated. The indication has since been extended to newly diagnosed Ph+ CML-CP.

Under this latest indication extension, Scemblix can now also be used to treat adult Ph+ CML-CP patients who possess a specific genetic modification known as the T315I mutation. The carriers of this mutation are resistant to many other treatments.
Since Ph+ CML is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

The active substance in Scemblix is a member of the tyrosine kinase inhibitor (TKI) group of medicines. Scemblix works by blocking an enzyme called BCR::ABL1 tyrosine kinase, which is constantly activated in this disease as a result of a genetic mutation and which promotes the growth of cancer cells. By blocking this enzyme, Scemblix can help to slow or stop this growth, and thus to control the disease symptoms.

Administration

Scemblix is a prescription-only medicine and should be prescribed by a doctor with experience in administering cancer treatments.

Scemblix is available as a film-coated tablet and is taken orally. The recommended dosage for patients with the T315I mutation is 200 mg twice daily at approximately 12-hour intervals. The tablets should be swallowed whole with a glass of water and should be taken without food.

Efficacy

The efficacy of Scemblix was investigated in a study named CABL001X2101. A total of 70 patients with CML-CP and harbouring a T315I mutation were included in this study. 48 of these patients were treated with the recommended dose of 200 mg twice daily. Most of the patients had received at least two prior lines of treatment with a tyrosine kinase inhibitor. Efficacy was primarily determined by measuring molecular response (MMR), i.e. a decline in BCR::ABL1 to a level below a particular maximum.

The results showed that 42.2 % of the patients achieved an MMR by week 24. This MMR rate by week 96 remained stable in 48.9 % of patients.

Precautions, undesirable effects, & risks

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

The most common undesirable effects in patients were muscle and joint pain (33 %), fatigue (25 %), upper respiratory tract infections (24 %), headache (22 %) and diarrhoea (20 %). Severe undesirable effects can include anaemia (13 %), increased pancreatic enzymes (19 %) and high blood pressure (16 %).

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

Why the medicinal product has been authorised

Many conventional tyrosine kinase inhibitors are ineffective in adult Ph+ CML-CP patients with a T315I mutation. The durable response rates observed in this difficult-to-treat group of patients were considered clinically meaningful.

Taking all the risks and precautions into account, and based on the available data, the benefits of Scemblix outweigh the risks. Swissmedic has therefore authorised the extension of indication for Scemblix with the active substance asciminib in adult Ph+ CML-CP patients with a T315I mutation in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Scemblix®

Information for patients (package leaflet): Information for patients Scemblix®
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.

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