swissmedic

Summary report on authorisation dated 12 August 2025

Scemblix® (active substance: asciminib)

Indication extension in Switzerland: 31 January 2025

Film-coated tablets for the treatment of adults who have been newly diagnosed with or previously treated for chronic-phase Philadelphia chromosome-positive chronic myeloid leukaemia

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.

Scemblix is intended either for patients who have been newly diagnosed or for patients who have already been treated with certain other medicines.

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.

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.

This indication extension for Scemblix was authorised under Project Orbis. Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. In addition to the FDA, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Canada (HC), Israel (MOH), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are currently represented in Project Orbis.

Mode of action

The active substance in Scemblix is a member of the tyrosine kinase inhibitor (TKI) group of medicines. Asciminib works by blocking the activity of a TKI enzyme called BCR::ABL1, which occurs in people with Ph+ CML as a result of a genetic modification.

Because BCR::ABL1 is constantly active, it promotes growth of the 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 of administering cancer treatments.

Scemblix is available as a film-coated tablet and is taken orally. The recommended total daily dose is 80 mg, taken either once a day or divided into two 40-mg doses taken 12 hours apart. The tablets should be swallowed whole with a glass of water and should be taken without food.

Efficacy

The efficacy of Scemblix in newly diagnosed Ph+ CML-CP was investigated in the J12301 study with 405 patients. Half the patients received asciminib, while the control group received a different tyrosine kinase inhibitor (TKI). The doctors had a choice of several TKIs.

Efficacy was primarily determined by measuring molecular response, i.e. a decline in BCR::ABL1 to a level below a particular maximum.

Molecular response to Scemblix was better than to the other TKIs, with 67.7% of patients who received Scemblix achieving a clear molecular response after 48 weeks compared with 49.0% in the control group. A further study (AUS08) in Ph+ CML-CP patients who had previously been treated with TKIs also showed a good molecular response to treatment with Scemblix. The results corroborate the efficacy of Scemblix in different stages of Ph+ CML-CP treatment.

Precautions, undesirable effects, & risks

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

The most common undesirable effects include musculoskeletal pain (33%), low blood platelet levels (thrombocytopenia) (28%), infections of the upper respiratory tract (24%), headaches (22%) and low white blood cell levels (neutropenia) (22%).

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

Scemblix offers an additional effective treatment option alongside the TKIs already in use for adults with newly diagnosed or previously treated Ph+ CML-CP. 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 the indication for Scemblix with the active substance asciminib in first- and second-line treatment of Ph+ CML-CP 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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