swissmedic

Public Summary SwissPAR dated 19 September 2022

Scemblix® (active substance: asciminib)

First authorisation in Switzerland: 9 June 2022

Medicinal product for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia

Information on authorisation

The medicinal product Scemblix contains the active substance asciminib. It is used for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML). Scemblix is used when two or more previous treatments with other medicinal products did not result in the desired treatment response or were poorly tolerated.

Ph+ CML is a type of blood cancer in which the body produces excessive amounts of abnormal white blood cells. Scemblix inhibits the action of a protein of the abnormal white blood cells and stops their division and growth.

Scemblix was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Scemblix was submitted for assessment to the regulatory authorities in Singapore, Australia, Canada, the United Kingdom and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation. Accordingly, and since Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report), it cannot issue a complete Public Summary SwissPAR. Swissmedic therefore refers to the relevant publications issued by the authorities involved.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Since this 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.

Why the medicinal product has been authorised

There are limited treatment options available for patients with Ph+ CML. Over time, intolerances or resistance to treatments can develop in patients, meaning there is a considerable need for therapies with new mechanisms of action.

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 medicinal product Scemblix, containing the active substance asciminib, for treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia.

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 Public Summary SwissPAR.

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.