swissmedic

Public Summary SwissPAR dated 6 September 2024

Vabysmo® (active substance: faricimab)

Indication extension in Switzerland: 11 July 2024

Medicinal product (solution for injection) for the treatment of macular oedema secondary to retinal vein occlusion

Information on authorisation

The medicinal product Vabysmo contains the active substance faricimab.

Vabysmo is used to treat macular oedema (collection of fluid in the retina (macula)), which occurs secondary to retinal vein occlusion (blockage of one or more branches of the retinal vein (BRVO) or blockage of the central retinal vein (CRVO)).

Vabysmo is a solution for injection for intravitreal administration. This means that the medicinal product is injected directly into the eye affected.

As in the case of the first authorisation, the indication extension for Vabysmo was also 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 to extend the indication of Vabysmo was submitted for assessment to the regulatory authorities in Australia, Canada, Singapore, 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).

Swissmedic authorised Vabysmo for the treatment of neovascular macular degeneration and diabetic macular oedema on 25 May 2022.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Vabysmo®

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.