swissmedic

Public Summary SwissPAR dated 17 August 2022

# Vabysmo® (active substance: faricimab)

First authorisation in Switzerland: 25 May 2022

Medicinal product for the treatment of neovascular macular degeneration and diabetic macular oedema

## Information on authorisation

The medicinal product Vabysmo contains the active substance faricimab.

It is used for the treatment of the progressive eye disease neovascular (wet) age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DMO).

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

Vabysmo 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 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).

## Why the medicine has been authorised

Treatment with Vabysmo demonstrably improves visual acuity and reduces vision loss in patients with neovascular macular degeneration or diabetic macular oedema.
Taking all the risks and precautions into account, and based on the available data, the benefits of Vabysmo outweigh the risks.

Swissmedic has therefore authorised the medicinal product Vabysmo, containing the active substance faricimab, for the treatment of neovascular macular degeneration and diabetic macular oedema.

## 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.