

Public Summary SwissPAR dated 13 December 2023

Vafseo[®] (active substance: vadadustat)

First authorisation in Switzerland: 19 June 2023

Medicinal product (film-coated tablet) for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults

Information on authorisation

The medicinal product Vafseo contains the active substance vadadustat.

It is used in adults to treat the symptoms of anaemia (lack of red blood cells) caused by chronic kidney disease (CKD). Due to their illness, the patients are dependent on maintenance dialysis¹.

Vafseo 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. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been made in at least two of the five countries.

The authorisation application for Vafseo was submitted to the drug regulatory authorities in the United Kingdom, Australia, 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 – a detailed report for professionals), 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 \(swissmedic.ch\)](https://www.swissmedic.ch).

¹ Dialysis: Dialysis is a procedure used in patients with renal insufficiency to clean the blood (blood washing). Maintenance dialysis extends the lives of patients with kidney failure or chronic kidney disease.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Vafseo, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzerland, the Information for healthcare professionals will be

made available on the following website:
www.swissmedicinfo.ch

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.