swissmedic

Public Summary SwissPAR dated 20 December 2023

Elfabrio® (active substance: pegunigalsidase alfa)

First authorisation in Switzerland: 11 September 2023

Medicinal product (concentrate for solution for infusion) for enzyme replacement therapy in adults with Fabry disease

Information on authorisation

The medicinal product Elfabrio contains the active substance pegunigalsidase alfa.

It is used in adults to treat Fabry disease, which is a rare hereditary condition in which patients have too little of the enzyme alpha-galactosidase A. This enzyme helps to break down a fatty substance called globotriaosylceramide (lyso-Gb3). If the enzyme is not present, lyso-Gb3 cannot be broken down and accumulates in organs, which can lead to kidney failure and heart problems.

Since Fabry disease is a rare and life-threatening disease, the medicinal product Elfabrio has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Elfabrio was authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland.

The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Elfabrio in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) and has not conducted its own scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the Assessment Report and the short report issued by the reference authority: www.ema.europe.eu

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Elfabrio, 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.