swissmedic

Public Summary SwissPAR dated 18 February 2022

Nexviadyme® (active substance: avalglucosidase alfa)

First authorisation in Switzerland: 17 November 2021

Medicinal product for the treatment of late-onset Pompe disease (glycogen storage disease type II)

Information on authorisation

The medicinal product Nexviadyme contains the active substance avalglucosidase alfa. It is used as an enzyme replacement therapy[1] in Pompe disease.

Pompe disease is a rare glycogen storage disease[2]. It is characterised by a hereditary deficiency of the "lysosomal α glucosidase" or "acid maltase" enzyme, which is needed to break down glycogen in muscle cells. Due to the lack of this enzyme, glycogen builds up in the muscle cells of affected patients, causing progressive damage to these cells. Depending on the form of the disease, symptoms of this muscle damage (such as cardiac insufficiency, difficulty walking, breathing problems) can become noticeable as early as infancy or only in childhood/adolescence or adulthood. A distinction is therefore made between early and late-onset forms of the disease.

Nexviadyme was approved 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 Nexviadyme was submitted for assessment to the regulatory authorities in Australia, Canada 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.

[1] Enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

[2] Glycogen: Glycogen is an energy store in cells, particularly in human liver and muscle cells.

Swissmedic considered and accepted the assessments by the foreign reference authorities in its decision on the authorisation for late-onset Pompe disease. 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 publications issued by the authorities involved:

- Overview of the evaluation process by the Australian authority TGA: Australian prescription medicine decision summary
- Regulatory Decision Summary of the Canadian authority Health Canada: Regulatory Decision Summary – Health Canada

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" refers to important medicines for rare diseases.

Why the medicine has been authorised

Taking all the risks and precautions into account, and based on the available data, the benefits of Nexviadyme outweigh the risks.

Swissmedic has therefore authorised the medicinal product Nexviadyme with the active substance avalglucosidase alfa for the treatment of late-onset Pompe disease.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Nexviadyme®

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.