swissmedic

Public Summary SwissPAR dated 12 January 2023

Lamzede® (active substance: velmanase alfa)

Temporary authorisation in Switzerland: 26 August 2022

Medicinal product (powder for solution for infusion) for the treatment of non-neurological manifestations in patients with mild to moderate alpha-mannosidosis.

Information on authorisation

The medicinal product Lamzede, which contains the active substance velmanase alfa, is a powder for solution for infusion.

Lamzede is used as an enzyme replacement therapy to treat non-neurological manifestations[1] in patients with mild to moderate alpha-mannosidosis.

The features of the disease include bone abnormalities, muscle weakness, enlarged liver and spleen, distinctive facial features and intellectual disabilities. The severity of the symptoms varies between patients.

Alpha-mannosidosis is a rare hereditary disease that affects an estimated 1 in 500,000 to 1 in 1,000,000 people worldwide. The affected person lacks the alpha-mannosidase enzyme[2], which is essential for breaking down glycoproteins[3]. The disorder damages cells due to the build-up of mannose-rich oligosaccharides (complex sugars) in all of the body's tissues.

In deciding whether to authorise the medicinal product Lamzede, containing the active substance velmanase alfa, Swissmedic took into account the assessment of the European Medicines Agency (EMA) regarding certain aspects such as the clinical data, as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment report of a foreign partner authority, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator product.

www.ema.europa.eu

[1] Manifestation: The onset of the disease manifests itself in characteristic symptoms. These may also occur only after a symptom-free latency or incubation period.

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

[3] Glycoproteins: Glycoproteins are proteins made up of a protein and one or more carbohydrate groups (sugar groups).

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

The medicinal product Lamzede was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lamzede®

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.