swissmedic

Summary report on authorisation dated 10 April 2026

Agamree® (active substance: vamorolone)

Authorisation in Switzerland: 14 January 2026

Oral suspension for the treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older.

About the medicinal product

Agamree contains the active substance vamorolone. Agamree is used to treat Duchenne muscular dystrophy (DMD) in patients aged 4 years and older. DMD is a rapidly progressing form of muscular dystrophy[1] caused by inherited mutations in the X chromosome. For this reason, it almost always occurs in boys and young men. The disease often leads to death in young adulthood. An estimated 150 to 200 children and young adults are affected by DMD in Switzerland.

Since this is a rare and life-threatening disease, the medicine has been recognised as an orphan drug. "Orphan drug" is a designation given to medicinal products for the treatment of rare diseases.

Agamree was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product has already been 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 a determination of the extent to which the results can be adopted and 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 promptly as possible.

In deciding whether to authorise Agamree in Switzerland, Swissmedic accepted the assessment and approval decisions of European Medicines Agency (EMA) and the U.S. Food and Drug Administration (US FDA), and has not conducted its own complete and independent scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic

[1]Muscular dystrophy: An inherited condition in which the muscles gradually break down and weaken owing to the absence of important building blocks of healthy muscle cells.

refers to the Assessment Report and summary report issued by the reference authorities.

www.ema.europa.eu; www.fda.gov

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Agamree®

Information for patients (package leaflet): Information for patients Agamree®
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 Summary report on authorisation.

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.