swissmedic

Summary report on authorisation dated 10 October 2025

Voxzogo® (active substance: vosoritide)

Authorisation in Switzerland: 30 January 2025

Powder and solvent for solution for injection for the treatment of achondroplasia in patients aged 4 months and older whose bones are still growing.

About the medicinal product

The medicinal product Voxzogo contains the active substance vosoritide. This active substance is similar to a protein produced by the body. Voxzogo is used to treat achondroplasia in patients aged 4 months and older whose growth plates are not yet closed. Voxzogo is intended for subcutaneous administration.

Achondroplasia is a genetic disease in which the growth of almost all bones in the body, including the skull, spine, arms and legs, is impaired.

Achondroplasia is the commonest form of dwarfism and is caused by a mutation in the FGFR3 gene. The modified gene leads to a cartilage formation disorder that impairs bone growth by means of premature ossification. Patients with achondroplasia often experience complications related to the bone growth disorder.

Before administering Voxzogo, doctors will conduct genetic tests to confirm the diagnosis of achondroplasia.

Voxzogo counteracts the growth impairment and helps promote bone growth.

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

In deciding whether to authorise the medicinal product Voxzogo, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of foreign authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Summary Report on authorisation are not met. Swissmedic refers to the authorisation of the foreign reference authorities.

www.ema.europa.eu

www.fda.gov

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Voxzogo®

Information for patients (package leaflet): Information for patients Voxzogo®
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.