swissmedic

Summary report on authorisation dated 15 September 2026

Ogsiveo® (active substance: nirogacestat)

Authorisation in Switzerland: 19 May 2026

Film-coated tablets for the treatment of adults with progressing desmoid tumours who require systemic treatment

About the medicinal product

Ogsiveo contains the active substance nirogacestat and is used to treat adult patients with progressing desmoid tumours who require systemic treatment.

Desmoid tumours are soft tissue tumours that form in fibrous connective tissue (usually in the arms, legs or abdomen) and that do not spread to other parts of the body.

Since this is a rare and life-threatening or chronically debilitating disease, the medicinal product Ogsiveo was authorised as an orphan drug. The term "orphan drug" refers to medicinal products used to treat patients with rare diseases.

Ogsiveo was authorised under Article 13 of the Therapeutic Products Act (TPA). This authorisation procedure is applied in certain circumstances when a medicinal product is already authorised in another country with comparable medicinal product control.

In such cases, Swissmedic may take account of the results of the assessments conducted by that country's medicinal products regulatory authority. These involve checks on the quality, efficacy, and safety of the medicinal product, and deciding whether 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 Ogsiveo in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA). Swissmedic has not, therefore, conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report and summary report issued by the reference authority.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ogsiveo®

Information for patients (package leaflet): Information for patients Ogsiveo®

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.