swissmedic

Summary report on authorisation dated 6 December 2024

Tegsedi® (active substance: inotersen)

Authorisation in Switzerland: 31 May 2021

Solution for injection in a pre-filled syringe for treatment of stage 1 or 2 polyneuropathy in adults with hereditary transthyretin amyloidosis (hATTR).

About the medicinal product

Tegsedi contains the active substance inotersen.
Tegsedi is used in adults to treat nerve damage (stage 1 and 2) caused by hereditary transthyretin amyloidosis (hATTR).
In this genetic disease, proteins called "amyloids" accumulate in the body tissues, including the nerve tissue. This accumulation impairs their function. Nerve damage (polyneuropathy) is particularly common.
Tegsedi acts as an "antisense oligonucleotide inhibitor", which reduces the production of tranthyretin (TTR) in the liver, thereby lowering the risk of harmful deposits of this protein forming and causing symptoms.
Since hATTR is a rare, life-threatening disease, the medicinal product Tegsedi has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Tegsedi has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in at least one other 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 the extent to which 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 Tegsedi in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMA/381704/2018) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the reference authority: www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tegsedi®

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

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.