Medicine Shortage Communication

3 July 2026

TEGSEDI® (inotersen sodium, 284 mg solution for injection in pre-filled syringe): planned marketing cessation (discontinuation)

Dear Healthcare Professional,

Akcea Therapeutics Ireland Limited would like to inform you of the permanent discontinuation of TEGSEDI (inotersen sodium) in the European Union (EU) from 01 December 2026 onwards.

Overview of situation

- **Akcea Therapeutics Ireland Limited is discontinuing Tegsedi based on a commercial decision (low utilisation of the product and natural attrition to other commercialised therapies). Submission of the marketing authorisation withdrawal is planned for 01 Dec 2026.**
- **The discontinuation affects all EU countries where the product is marketed, specifically Austria, Bulgaria, France, Germany, Greece, Ireland, Italy, Luxembourg, Poland, Portugal, Spain, and Sweden. National withdrawal submissions will be carried out in these countries where the product is marketed and are planned according to national lead time requirements.**
- **This discontinuation will be permanent.**
- **The product discontinuation is not due to any safety, efficacy or quality concerns with TEGSEDI®**

Mitigation measures

In order to manage the product discontinuation, the marketing authorisation holder is engaging with the European Medicines Agency and the National Competent Authorities to provide sufficient time to alert national agencies and for healthcare professionals to prepare.

In preparation for the product discontinuation, healthcare professionals should:

- **Not prescribe Tegsedi to new patients.**
- **Transition all patients who are currently taking TEGSEDI to an appropriate commercially available treatment alternative indicated to treat stage 1 or**

Stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR).

- **Consult EMA's shortage catalogue, their respective country's shortage register published on Italian Medicines Agency's portal (AIFA) or their respective national competent authority (AIFA) for additional information.**

Background on the shortage

Akcea Therapeutics Ireland Limited will be permanently discontinuing TEGSEDI (inotersen) in the EU and submitting the marketing authorisation withdrawal on 01 December 2026. This is a commercial decision based on low utilisation of the product and is not related to manufacturing, quality, or safety matters associated with TEGSEDI. Akcea believes this withdrawal will not deprive patients diagnosed with polyneuropathy of hereditary ATTR from appropriate treatment since there are several approved and available treatment alternatives.

Company contact point

Suspected adverse drug reactions may be reported to the marketing authorisation holder, via adverseevent@ionis.com.

The distributor's (Sobi) medical information department may also be contacted at +46 8 697 20 00 or medical.info@sobi.com if there are any questions about the information contained in this letter. This letter is not intended as a complete description of the benefits and risks related to the use of TEGSEDI. Please refer to the enclosed Summary of Product Characteristics.

For more information about Sobi, please call +46 8 697 20 00 or visit www.sobi.com. For more information about Ionis Pharmaceuticals, please call 1-760-931-9200 or visit www.ionispharma.com.