INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient is receiving Tegsedi for the treatment of hereditary transthyretin amyloidosis with symptoms of polyneuropathy.

Tegsedi has a risk of thrombocytopenia, glomerulonephritis and hepatotoxicity, and the potential risks of ocular toxicity due to vitamin A deficiency and liver transplant rejection.

Patients treated with Tegsedi should have their platelet count monitored at least every 2 weeks during the entire course of treatment (see Summary of Product Characteristics (SmPC)), and urine protein to creatinine ratio (UPCR) and eGFR should be monitored every 3 months or more frequently, as clinically indicated, based on history of chronic kidney disease and/or renal amyloidosis (see SmPC).

Platelet count, UPCR and eGFR should be monitored for 8 weeks following discontinuation of treatment.

Hepatic enzymes should be measured 4 months after initiation of treatment with Tegsedi and annually thereafter or more frequently as clinically indicated, in order to detect cases of hepatic impairment.

Patients with a prior liver transplant should be monitored for signs and symptoms of transplant rejection during treatment with Tegsedi. In these patients, liver function tests should be performed monthly (see SmPC).

If platelet count falls below 25 x 10^9/L, Tegsedi treatment should be permanently discontinued and corticosteroid therapy is recommended.

If glomerulonephritis is confirmed, Tegsedi treatment should be permanently discontinued and early initiation of immunosuppressive therapy should be considered.

Tegsedi is contraindicated in patients with severe hepatic impairment.

Liver function should be assessed before initiating Tegsedi. Prompt clinical evaluation and measurement of liver function tests should be performed preferably within 72 hours upon report of symptoms of liver injury.

Dose interruption should be considered until clinical and liver function evaluation is performed.

If patient develops drug-induced liver injury, Tegsedi treatment should be permanently discontinued.

If patients develop ocular symptoms consistent with vitamin A deficiency, referral for ophthalmological assessment is recommended.

Discontinuation of Tegsedi should be considered in patients who develop liver transplant rejection during treatment.

Patient Alert Card

Have this card with you at all times during treatment with Tegsedi and for 8 weeks after stopping treatment.

Show it to any doctor that sees you and when you go to the hospital.

Tegsedi® (inotersen) injection 284 mg/1.5 mL

PATIENT INFORMATION

Tegsedi may cause side effects that are severe or life-threatening.

Call your doctor immediately or seek urgent medical attention if any of the signs below appear.

IMPORTANT SIGNS AND SYMPTOMS OF THROMBOCYTOPENIA OR GLOMERULONEPHRITIS MAY INCLUDE:

- Unexplained bruising or a rash of tiny reddish-purple spots, often on the lower legs
- Bleeding from skin cuts that does not stop or oozes
- Bleeding from your gums or nose
- Blood in urine or stools
- Bleeding into the whites of your eyes
- Sudden severe headaches or neck stiffness
- Blood in your urine or brown urine
- Foamy urine (proteinuria)
- Passing less urine than usual

In addition to the above, call your doctor if any of the signs below appear.

SIGNS AND SYMPTOMS OF OCULAR TOXICITY DUE TO VITAMIN A DEFICIENCY MAY INCLUDE:

- Dry eyes
- Poor vision
- Decreased vision at night
- Swollen eyes
- Hazy or cloudy eyes

SIGNS AND SYMPTOMS OF LIVER INJURY OR LIVER TRANSPLANT REJECTION MAY INCLUDE:

- Fever
- Yellowing of the skin or eyes (jaundice)
- Dark urine
- Abdominal pain
- Right upper abdominal discomfort
- Fatigue
- Bleeding or bruising more easily than normal
- Loss of appetite

Remember to follow all blood, urine and liver function tests arranged by your doctor and keep a list of all other medicines you are taking for any visit to a doctor.

Keep the card with you at all times during Tegsedi treatment and for at least 8 weeks after discontinuing Tegsedi treatment.

Prescribing Doctor's Name:

_____

Contact details:

_____

_____

_____

REPORTING SIDE EFFECTS

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: **www.hpra.ie**. Side effects can also be reported to Swedish Orphan Biovitrum Ltd at **medical.info.uk@sobi.com** or by calling +44 (0) 800 111 4754.
By reporting side effects you can help provide more information on the safety of this medicine.

sobi

NP-42120
Date of preparation: July 2025
Date of approval: July 2025