Patient Alert Card

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

Please show it to any doctor that sees you and when you go to the hospital

Tegsedi® (inotersen) injection 284 mg/1.5 mL ▼ sobi

INFORMATION FOR HEALTHCARE PROFESSIONALS (HCPs)

This patient is receiving Tegsedi for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR).

Tegsedi has a risk of thrombocytopenia and glomerulonephritis, and the potential risk 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 (see Summary of Product Characteristics (SmPC), accessible at medicines.ie) 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.
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.

Tegsedi is distributed by Sobi Ltd on behalf of Akcea Therapeutics Ireland Limited, the Marketing Authorisation Holder for Tegsedi in the Republic of Ireland

PATIENT INFORMATION

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

Call your doctor or go to the emergency room 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 transplant rejection may include:

- Fever
- Yellowing of the skin or eyes (jaundice)
- Dark urine
- Abdominal pain
- Fatigue

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 this 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:

IMPORTANT INFORMATION

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Reporting forms and information can be found at www.hpra.ie

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