Tegsedi™ ▼
(inotersen) injection

Patient Alert Card

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

Please show it to any doctor, nurse, dentist or pharmacist that sees you and when you go to hospital.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting an side effects you may get.

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IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS (HCPs)

Inotersen is indicated for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR).

Inotersen may cause thrombocytopenia, glomerulonephritis and ocular toxicity due to vitamin A deficiency and liver transplant rejection.

Patients treated with inotersen should have their platelet count monitored at least every 2 weeks (see Summary of Product Characteristics (SmPC), accessible at: https://www.medicines.org.uk/emc/product/10011), 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 inotersen 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 inotersen. In these patients, liver function tests should be performed monthly (see SmPC).

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

If glomerulonephritis is confirmed, inotersen 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 inotersen 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 United Kingdom

IMPORTANT PATIENT INFORMATION

Inotersen may cause severe or life-threatening side effects including thrombocytopenia (reduced numbers of blood clotting cells), glomerulonephritis (kidney inflammation), ocular toxicity due to vitamin A deficiency and liver transplant rejection.

You should contact your doctor immediately or seek urgent medical attention if you experience any of the following symptoms or signs:

- 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 dark/brown urine
- Foamy urine (proteinuria)
- Passing less urine than usual
- Dry eyes
- Poor vision
- Decreased vision at night
- Swollen eyes
- Hazy or cloudy eyes
- Fever
- Yellowing of the skin or eyes (jaundice)
- Abdominal pain
- Fatigue

It is important that you provide blood, urine and liver function tests as requested by your doctor. Keep a list of all of your medicines and show it to any doctor, nurse, dentist, pharmacist or any other healthcare professional that sees you.

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

Prescribing doctor's name:

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Contact details:

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If you require further information, please contact the National Amyloidosis Centre:

National Amyloidosis Centre
Royal Free London NHS Foundation Trust
Lower 3rd floor
Rowland Hill Street, NW3 2PF

Nurse helpline: 0779 098 9695
(Monday–Friday: 09:00–17:00)
After hours: Consultant on call for emergency advice for amyloidosis, available via Royal Free Hospital switchboard (020 3758 2000).

REPORTING SIDE EFFECTS

You can help by reporting any side effects you may get. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Alternatively, search for MHRA Yellow Card in the Google Play or Apple App Store, or contact the MHRA at https://yellowcard.mhra.gov.uk/ or 0800 731 6789.

NP-22343
Sep 2022