IMDYLLTRA® ▼(tarlatamab) PATIENT CARD

TO BE COMPLETED BY THE PRESCRIBING DOCTOR

THIS PATIENT HAS RECEIVED IMDYLLTRA®

Patient name / phone number

Date and time of first IMDYLLTRA® infusion

Prescribing doctor name / phone number

Name of hospital / centre / institution

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance www.hpra.ie. Adverse reactions/events should also be reported to Amgen Limited on +44 (0)1223 436441 or Freephone 1800 535 160.

[This Patient Card fulfills the conditions of the marketing authorization and has been approved by the competent authority.]

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IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

- This patient is being treated with tarlatamab, which is a bispecific T-cell engager (BiTE®) molecule.
- Tarlatamab is used for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- Tarlatamab may cause side effects which may be severe and life-threatening such as cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS).

Further information on IMDYLLTRA® is available at:

https://www.medicines.ie/medicines/imdylltra-1-mg-powder-for-concentrate-and-solution-for-solution-for-infusion-36760/spc

https://www.medicines.ie/medicines/imdylltra-10-mg-powder-for-concentrate-and-solution-for-solution-for-infusion-36761/spc

If this patient is experiencing any of the signs or symptoms on this card, please contact the prescribing doctor immediately for further information.

IMPORTANT INFORMATION FOR PATIENTS/CAREGIVERS

Tarlatamab can cause serious and/or life-threatening side effects, such as cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS).

Call your prescribing doctor or seek emergency medical attention immediately if you experience ANY of these signs and symptoms.

- Fever (38.0ºC or higher)
- Hypotension (low blood pressure)
- Shortness of breath, trouble breathing
- Fast or irregular heartbeat: palpitations
- Confusion, trouble speaking, memory loss or personality changes
- Dizziness or lightheadedness
- Headache
- Chills
- Nausea or vomiting
- Seizure
- Loss of balance, weakness, numbness
- Extreme sleepiness or decreased consciousness
- Shakiness of your hands or limbs (tremor)

These are not all of the possible side effects of tarlatamab. Please refer to the Package Leaflet for a full list of possible side effects. You should always consult your prescribing doctor about taking other medications while taking tarlatamab.

IMPORTANT INFORMATION FOR PATIENTS/CAREGIVERS

You are required to stay within proximity of an appropriate healthcare setting such as the treatment hospital for 24 hours from the start of each tarlatamab infusion on Day 1 and Day 8, accompanied by a caregiver.

CONTACT your prescribing doctor if you experience any of the signs and symptoms listed in this card.

SEEK emergency help if you cannot reach your prescribing doctor's office.

DO NOT drive or operate machinery if neurologic symptoms, such as dizziness, seizures and confusion occur until the symptoms resolve.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.