Package leaflet: Information for the patient

IMDYLLTRA 1 mg powder for concentrate and solution for infusion
IMDYLLTRA 10 mg powder for concentrate and solution for infusion

tarlatamab

▼This medicine 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What IMDYLLTRA is and what it is used for

The active ingredient in IMDYLLTRA is tarlatamab. This belongs to a group of medicines called antineoplastic agents which target cancer cells.

IMDYLLTRA is used to treat adults with small cell lung cancer (SCLC) that has spread throughout the lungs and/or to other parts of the body.

IMDYLLTRA can only be prescribed if you have previously been treated with two other types of treatments and they did not work or are no longer working.

How does IMDYLLTRA work?

IMDYLLTRA is different to chemotherapy. IMDYLLTRA works with your immune system to find and destroy small cell lung cancer cells.

If you have any questions about how IMDYLLTRA works or why this medicine has been prescribed for you, ask your doctor, pharmacist or nurse.

2. What you need to know before you use IMDYLLTRA

Do not use IMDYLLTRA
- if you are allergic to tarlatamab or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before you are given IMDYLLTRA.

Warnings and precautions

Tell your doctor, pharmacist or nurse immediately if you experience any of the following while receiving IMDYLLTRA as they may need to treat the symptoms:

- Cytokine Release Syndrome (CRS)
    - Fever
    - Low blood pressure (hypotension)
    - Shortness of breath: confusion, restlessness, trouble breathing
    - Fast or irregular heartbeat: palpitations, dizziness
    - Headache
    - Chills
    - Nausea
    - Vomiting
- Neurological problems – Immune effector cell-associated neurotoxicity syndrome (ICANS)
    - Headache
    - Trouble speaking, memory loss, personality changes (encephalopathy)
    - Confusion
    - Feeling disoriented or having the inability to think clearly (delirium)
    - Seizure
    - Loss of balance or coordination (ataxia)
    - Weakness or numbness of arms and legs (neurotoxicity)
    - Shakiness of your hands of limbs (tremor)
    - Tiredness or feeling sleepy
- Neutropenia (low white blood cell count)
    - Chills or shivering
    - Feel warm
    - High body temperature
- Allergic reaction (hypersensitivity)
    - Rash
    - Trouble breathing

Your doctor or nurse will monitor for signs and symptoms of these reactions during and after the infusion.

Children and adolescents
IMDYLLTRA has not been studied in children or adolescents. Treatment with IMDYLLTRA is currently not recommended in patients under 18 years of age.

Other medicines and IMDYLLTRA
Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and , breast-feeding and fertility
The effects of IMDYLLTRA in pregnant women are not known.

Tell your doctor or nurse if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Your doctor will help you weigh the benefits against the risk of taking IMDYLLTRA while you are pregnant.

Tell your doctor or nurse if you become pregnant during treatment with IMDYLLTRA. Your doctor may need to talk to you about potential risks.

Women who are able to become pregnant should use effective contraception during treatment and for at least 28 days after your last dose. Talk to your doctor or nurse about suitable methods of contraception.

It is not known whether the ingredients of IMDYLLTRA pass into breast milk. Tell your doctor or nurse if you are breast-feeding or are planning to breast-feed. You should not breast-feed during treatment with IMDYLLTRA and for at least 28 days after your last dose.

Driving and using machines
Refrain from driving, and operating heavy or potentially dangerous machinary and engaging in hazardous occupations or activities following IMDYLLTRA infusion, if there are ICANS-associated neurological symptoms, such as dizziness, seizures, and confusion, until these symptoms resolve.

3. How to use IMDYLLTRA

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How IMDYLLTRA is given
IMDYLLTRA will be given to you through a vein (intravenous) as a 1-hour infusion.

IMDYLLTRA will be given on the following schedule: Day 1, Day 8, Day 15, and then every 2 weeks thereafter. One hour before receiving your first two doses of IMDYLLTRA you will be given a medicine call dexamethasone. This will be given to you by intravenous (IV) infusion into your vein. You may also get IV fluids after your first two doses of IMDYLLTRA.

Your doctor will determine how long you should stay on IMDYLLTRA.

Your doctor may delay of completely stop treatment with IMDYLLTRA if you have certain side effects.

Your doctor will monitor you for 16 hours after the first infusion of IMDYLLTRA (Day 1).

You should plan to stay within 1 hour of the hospital for 24 hours starting from each IMDYLLTRA infusion on Day 1 and Day 8 and have a caregiver with you.You and your caregiver will be given a Patient Alert Card (PAC) which contains instructions on the signs and symptoms of Cytokine Release Syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).

After the third infusion (Day 15), and for all future infusions your doctor will provide information about how long you may need to be monitored after the infusion of IMDYLLTRA.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you get any of the following or combination of the following side effects:

- neurologic events: shaking (or tremor), confusion, disturbances of brain function (encephalopathy), difficulty in communicating (aphasia), seizure (convulsion).

- fever, swelling, chills, decreased or increased blood pressure and fluid in the lungs, which may become severe - these may be signs of a so-called cytokine release syndrome.

Other side effects include:

Very common side effects (may affect more than 1 in 10 people)
- decreased levels of red blood cells (anaemia)
- constipation
- nausea
- fever (pyrexia)
- tiredness (fatigue)
- physical weakness or lack of energy (asthenia)
- decreased levels of white blood cells (neutrophil count decrease)
- decreased appetite
- low level of sodium in blood (hyponatremia)
- bad taste in mouth (dysgeusia)
- dry or wet cough, shortness of breath (dyspnea)

Common (may affect more than 1 in 100 people):
- change in normal activity or nervous system (neurotoxicity)
- shakiness of hands and limbs (tremor)
- confusion (confusional state)
- feeling disoriented (delirium)

Reporting of side effects
If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store IMDYLLTRA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Unopened Vials:
- Store and transport refrigerated (2°C - 8°C).
- Do not freeze.
- Store in the original carton in order to protect from light.

Prepared IMDYLLTRA (infusion bag)
- Once at room temperature 23°C to 27°C, store no longer than 8 hours.
- When refrigerated (2°C to 8°C), the infusion bag must be used within 7 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What IMDYLLTRA contains
- The active substance is tarlatamab.
- The other ingredients are sucrose, polysorbate 80, L-glutamic acide, and sodium hydroxide.
- The IV Solution Stabiliser contains citric acid monohydrate, lysine hydochloride, polysorbate 80, sodium hydroxide to adjust pH to 7.0 and water for injection.

What IMDYLLTRA looks like and contents of the pack
IMDYLLTRA is a powder for concentrate and solution for infusion.
- 1 mg pack contains: 1 glass vial of 1 mg IMDYLLTRA and 2 vials of 7 mL IV Solution Stabiliser.
- 10 mg pack contains: 1 glass vial of 10 mg IMDYLLTRA and 2 vials of 7 mL IV Solution Stabiliser.

Sterile Water for Injection (not included) should be used to reconstitute IMDYLLTRA.

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This leaflet was last revised in October 2024.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.