IMDELLTRA®

This medicine has provisional approval in Australia for the treatment of adults with advanced small cell lung cancer. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being given Imdelltra?

Imdelltra contains the active ingredient tarlatamab. Imdelltra is used to treat adults with small cell lung cancer that has spread throughout the lungs and/or to other parts of the body, and who have received treatment with chemotherapy that contains platinum and it did not work or is no longer working. For more information, see Section 1. Why am I being given Imdelltra? in the full CMI.

2. What should I know before I am given Imdelltra?

Do not use if you have ever had an allergic reaction to tarlatamab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given Imdelltra? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Imdelltra and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given Imdelltra?

Imdelltra is given by your doctor or nurse as an intravenous infusion for 1 hour.

More instructions can be found in Section 4. How will I be given Imdelltra? in the full CMI.

5. What should I know while I am being given Imdelltra?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are being given Imdelltra. • Tell your doctor if you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant. Use birth control during treatment and for 2 months after your last dose.
Things you should not do	• Do not breastfeed during treatment with Imdelltra and for at least 2 months after your last dose.
Driving or using machines	• Refrain from driving, operating heavy or potentially dangerous machinery and engaging in hazardous occupations or activities following Imdelltra infusion.

For more information, see Section 5. What should I know while I am being given Imdelltra? in the full CMI.

6. Are there any side effects?

Common side effects include: decreased appetite, fever, constipation, weakness or lack of energy, bad taste in mouth, tiredness, nausea, cough, low sodium in blood. Serious side effects can include infusion-related reaction, neurologic problems including immune effector cell-associated neurotoxicity syndrome (ICANS), decreased blood cell counts and allergic reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

This medicine has provisional approval in Australia for some patients with small cell lung cancer. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

WARNING: Imdelltra may cause side-effects that are serious, life-threatening or lead to death including Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Call your doctor and get medical attention immediately if you develop any of the signs or symptoms of CRS or ICANS listed below:

CRS: Fever, shortness of breath, confusion, restlessness, trouble breathing, tiredness, fast or irregular heartbeat, palpitations, dizziness, headache, chills, nausea and vomiting.

ICANS: trouble speaking, memory loss, personality changes, confusion, feeling disoriented or having difficulty thinking clearly, seizure, loss of balance or coordination, weakness or numbness of arms and legs, shakiness of hands or limbs, headache.

Imdelltra®

Active ingredient: *tarlatamab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Imdelltra. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Imdelltra.**

Where to find information in this leaflet:

1. Why am I being given Imdelltra?
2. What should I know before I am given Imdelltra?
3. What if I am taking other medicines?
4. How will I be given Imdelltra?
5. What should I know while I'm being given Imdelltra?
6. Are there any side effects?
7. Product details

1. Why am I being given Imdelltra?

Imdelltra contains the active ingredient tarlatamab. Imdelltra belongs to a group of medicines called antineoplastic agents which target cancer cells. Imdelltra is different to chemotherapy. Imdelltra works with your immune system to find and destroy small cell lung cancer cells.

Imdelltra 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, and**
- **you have received treatment with chemotherapy that contains platinum, and it did not work or is no longer working.**

2. What should I know before I am given Imdelltra?

Warnings

Do not use Imdelltra if:

- you are allergic to tarlatamab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can be given this medicine.

Check with your doctor if you:

- have an infection
- have ever had an infusion reaction after previously using Imdelltra
- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy

Check with your doctor if you are pregnant or intend to become pregnant. The effects of Imdelltra in pregnant women are not known. Your doctor will help you weigh the benefit against the risk of taking Imdelltra while you are pregnant.

Women who are able to become pregnant should use birth control during treatment. You must also do this for 2 months after your last dose. Talk to your healthcare provider about suitable methods of birth control.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether the ingredients in Imdelltra pass into breast milk.

You should not breast-feed during treatment with Imdelltra and for at least 2 months after your last dose.

Children and adolescents

Imdelltra has not been studied in children or adolescents.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Imdelltra and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Imdelltra.

4. How will I be given Imdelltra?

Imdelltra will be given to you in a hospital or clinic under the supervision of an experienced doctor.

Imdelltra will be given to you by intravenous (IV) infusion into your vein for 1-hour.

How much you will be given

You will receive Imdelltra on a "step-up" dosing schedule. The step-up dosing schedule is when you receive a smaller dose of Imdelltra on Day 1 of your first treatment cycle (Cycle 1). Imdelltra is usually given as an initial dose of 1 mg on Day 1, followed by 10 mg doses thereafter.

If your dose of Imdelltra is delayed for any reason, you may need to repeat the “step-up dosing schedule”.

When you will be given Imdelltra

Imdelltra 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 Imdelltra you will be given a medicine called dexamethasone. This will be given to you by IV infusion into your vein. You may also get IV fluids after your first two doses of Imdelltra.

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

Your doctor may delay or completely stop treatment with Imdelltra if you have certain side effects.

Your doctor will monitor you for 16 hours from the start of the first infusion of Imdelltra (Day 1).

You should plan to stay within 1-hour of a healthcare facility for a total of 24 hours from the start of the Imdelltra infusion after your Day 1 and Day 8 of Cycle 1 doses and have a caregiver with you.

After the second infusion (Day 8), and for all future infusions your doctor will inform you about how long you may need to be monitored after the infusion of Imdelltra.

If you miss a dose of Imdelltra, call your doctor right away to reschedule. It is very important that you do not miss a dose.

If you are given too much Imdelltra

As Imdelltra is given to you under the supervision of your doctor, it is unlikely that you will receive too much. If this happens, your doctor will monitor you for any signs or symptoms of side effects, and treat these symptoms if necessary.

However, if you think you have been given too much Imdelltra, tell your doctor or nurse immediately. You may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I'm being given Imdelltra?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Imdelltra.

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 Imdelltra while you are pregnant.

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

If you are able to become pregnant you should use birth control during treatment. You must also do this for 2 months after your last dose. Talk to your doctor about suitable methods of birth control.

Imdelltra has a Patient Alert Card and Patient Guide. These are available from your doctor or Amgen Medical Information. The guide and the card include important safety information that you should be aware of whilst on treatment with IMDELLTRA. You should always carry the card with you whilst on treatment.

Call your doctor straight away if you:

- Have signs or symptoms of possible side effects or if they get worse. See Section 6. Are there any side effects?

Driving or using machines

Refrain from driving, operating heavy or potentially dangerous machinery and engaging in hazardous occupations or activities following Imdelltra infusion in the event of neurological symptoms, such as dizziness, seizures, and confusion until they resolve.

Looking after your medicine

Imdelltra will be prepared by your pharmacist and stored in a refrigerator at 2°C - 8°C until infusion.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Constipation • Nausea • Fever • Tiredness • Physical weakness or lack of energy • Decreased appetite • Low level of sodium in the blood • Bad taste in mouth • Dry or wet cough, shortness of breath • Change in normal activity of nervous system • Shakiness of hands and limbs • Confusion • Feeling disoriented	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of an inflammatory condition: • fever • shortness of breath, confusion, restlessness, trouble breathing • tiredness • fast or irregular heartbeat, palpitations, dizziness • headache • chills • nausea • vomiting **Signs of neurologic events:** • trouble speaking, memory loss, personality changes • confusion • feeling disoriented or having difficulty thinking clearly • seizure • loss of balance or coordination • weakness or numbness of arms and legs • shakiness of your hands or limbs • headache **Signs of low white blood cells:** • chills or shivering • feeling warm • high body temperature **Signs of low red blood cells:** • tiredness • pale appearance • shortness of breath **Signs of an allergic reaction:** • rash • difficulty breathing	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Imdelltra contains

Active ingredient (main ingredient)	tarlatamab
Other ingredients (inactive ingredients)	**Imdelltra** Glutamic acid Sucrose Polysorbate 80 Sodium hydroxide **IV Solution Stabiliser** Citric acid monohydrate Lysine hydrochloride Polysorbate 80 Sodium hydroxide Water for injections

Do not receive this medicine if you are allergic to any of these ingredients.

What Imdelltra looks like

Imdelltra is a white to slightly yellow powder supplied in a glass vial containing 1 mg (AUST R 453165) or 10 mg (AUST R 453166) tarlatamab.

Who distributes Imdelltra

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

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