

For you & your caregiver

# IMDELLTRA® After the Infusion

Use this guide to keep track of important information and any side effects so you can keep your healthcare provider informed

Not actual people with ES-SCLC.

## What is IMDELLTRA® (tarlatamab-dlle)?

IMDELLTRA® is a prescription medicine used to treat adults with extensive stage small cell lung cancer (ES-SCLC), which is cancer that has spread throughout the lung 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. It is not known if IMDELLTRA® is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about IMDELLTRA®?

IMDELLTRA® can cause side effects that can be severe, life-threatening, or cause death, including:

- **Cytokine Release Syndrome (CRS).** CRS is common during treatment with IMDELLTRA® and can be severe, life-threatening, or cause death. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, including:
  - fever of 100.4°F (38°C) or higher
  - low blood pressure
  - tiredness
  - fast heartbeat or dizziness
  - headache
  - shortness of breath or trouble breathing
  - nausea and vomiting
  - confusion, restlessness, or feeling anxious
  - problems with balance and movement, such as trouble walking
  - heart, liver, or kidney problems
  - blood clots or unusual bleeding or bleeding that lasts a long time

Please see additional **Important Safety Information**, including **BOXED WARNINGS**, on pages 7–9.

**IMDELLTRA®**  
(tarlatamab-dlle) for injection  
1 mg & 10 mg single-use vials

You should remain within 1 hour of a healthcare setting for a total of 48 hours from the start of the IMDELLTRA® infusion after your Day 1 and Day 8 of Cycle 1 doses, accompanied by a caregiver.

You may experience serious side effects after your infusion. If any of the following signs and symptoms appear, take note of when they occur and call your healthcare provider.

#### Important Care Team Members and Contact Information

Name/Role: \_\_\_\_\_ Infusion Center Name/Role: \_\_\_\_\_  
Phone number: \_\_\_\_\_ Phone number: \_\_\_\_\_

#### CRS symptoms

CRS is common during treatment with IMDELLTRA® and can be severe, life-threatening, or cause death.

In clinical studies, 73% of CRS events in people who were given IMDELLTRA® occurred after the first dose, and 60% occurred after the second dose. 15% of CRS events happened after the third dose.

- Fever of 100.4 °F (38 °C) or higher
- Low blood pressure
- Tiredness
- Fast heartbeat or dizziness
- Headache
- Shortness of breath or trouble breathing
- Nausea and vomiting
- Confusion, restlessness, or feeling anxious
- Problems with balance and movement, such as trouble walking
- Heart, liver, or kidney problems
- Blood clots or unusual bleeding or bleeding that lasts a long time

Use the space on the next pages of this guide to take notes and track how you are feeling.

#### Neurologic problems

IMDELLTRA® can cause neurologic problems that can be severe, life-threatening, or cause death and may happen days or weeks after you receive IMDELLTRA®.

- Changes in taste
- Headache
- Numbness or tingling of your hands or feet
- Dizziness
- Trouble sleeping
- Muscle weakness or numbness of arms or legs
- Problems with walking, or loss of balance or coordination
- Trouble speaking, memory loss, or personality changes
- Confusion, feeling disoriented, slow thinking, or not being able to think clearly
- Fainting or loss of consciousness
- Seizures
- Shaking (tremors)
- Sleepiness
- Feeling like you have no energy

#### Signs of low blood cell counts to watch for post-infusion

Decreased blood cell counts can be severe and may include the following:

- Low white blood cell counts (neutropenia), which can increase your risk for infection
- Low red blood cell counts (anemia), which can cause tiredness and shortness of breath
- Low platelet counts (thrombocytopenia), which can cause bruising or bleeding problems

#### Signs of infection to watch for post-infusion

IMDELLTRA® can cause serious infections that can be life-threatening and cause death.

- Fever of 100.4 °F (38 °C) or higher
- Cough
- Chest pain
- Tiredness
- Shortness of breath
- Painful rash
- Sore throat or runny nose
- Pain during urination
- Feeling weak or generally unwell
- Yeast infections in the mouth or other areas

## Signs of liver problems to watch for post-infusion

- Tiredness
- Loss of appetite
- Pain in your right upper stomach area (abdomen)
- Dark urine
- Yellowing of your skin or the white part of your eyes

## When should I call my doctor's office?

Call your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, neurologic problems, infections, or liver problems.

## When should I go straight to the ER?

IMDELLTRA® can cause allergic reactions that can be severe. Go to the nearest emergency room or get help right away if you develop signs or symptoms of a severe allergic reaction during treatment, including:

- Shortness of breath or trouble breathing
- Pain or tightness in your chest or back
- Wheezing
- Coughing
- Feeling lightheaded or dizzy
- Rash

These are not all of the possible side effects of IMDELLTRA®. Call your doctor for medical advice about side effects.

## The most common side effects of IMDELLTRA® also include

The most common side effects of IMDELLTRA® also include:

- Tiredness
- Decreased appetite
- A bad or metallic taste in your mouth
- Fever
- Muscle or bone pain
- Constipation
- Nausea

**What is IMDELLTRA® (tarlatamab-dlle)?**

IMDELLTRA® is a prescription medicine used to treat adults with extensive stage small cell lung cancer (ES-SCLC), which is cancer that has spread throughout the lung 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. It is not known if IMDELLTRA® is safe and effective in children.

**IMPORTANT SAFETY INFORMATION****What is the most important information I should know about IMDELLTRA®?**

**IMDELLTRA® can cause side effects that can be severe, life-threatening or cause death, including:**

- **Cytokine Release Syndrome (CRS).** CRS is common during treatment with IMDELLTRA® and can be severe, life-threatening, or cause death. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, including:

- fever of 100.4°F (38°C) or higher
- low blood pressure
- tiredness
- fast heartbeat or dizziness
- headache
- shortness of breath or trouble breathing
- nausea and vomiting
- confusion, restlessness, or feeling anxious
- problems with balance and movement, such as trouble walking
- heart, liver, or kidney problems
- blood clots or unusual bleeding or bleeding that lasts a long time

**Due to the risk of CRS, you will receive IMDELLTRA® as per the following “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).
- You will receive the full treatment dose of IMDELLTRA® on Day 8 and Day 15 of Cycle 1. You will receive the full treatment dose 1 time every 2 weeks after Day 15 of Cycle 1.

- If your dose of IMDELLTRA® is delayed for any reason, you may need to repeat the “step-up dosing schedule”.
- Before receiving your Day 1 and Day 8 doses of Cycle 1 of IMDELLTRA®, you will be given a medicine to help reduce your risk of CRS. This will be given into your vein by intravenous (IV) infusion. You will also receive IV fluids after each of your Cycle 1 Day 1 and Day 8 doses. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.

- **Neurologic Problems.** IMDELLTRA® can cause neurologic problems that can be severe, life-threatening, or cause death. Neurologic problems may happen days or weeks after you receive IMDELLTRA®. Your healthcare provider may refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems, including:

- changes in taste
- headache
- numbness or tingling of your hands or feet
- dizziness
- trouble sleeping
- muscle weakness or numbness of arms or legs
- problems with walking, or loss of balance or coordination
- trouble speaking, memory loss, or personality changes
- confusion, feeling disoriented, slow thinking, or not being able to think clearly
- fainting or loss of consciousness
- seizures
- shaking (tremors)
- sleepiness
- feeling like you have no energy

**Due to the risk of CRS and neurologic problems, you will receive the following monitoring during treatment with IMDELLTRA®:**

- **For Day 1 and Day 8 Cycle 1 doses**, your healthcare provider will monitor you for **22 to 24 hours from the start of the IMDELLTRA® infusion in a healthcare setting** that can manage these side effects.
- **You should remain within 1 hour of a healthcare setting for a total of 48 hours** from the start of the IMDELLTRA® infusion after your Day 1 and Day 8 of Cycle 1 doses and be accompanied by a caregiver.
- **For Day 15 of Cycle 1 and Cycle 2 doses**, your healthcare provider will watch you for **6 to 8 hours** after the IMDELLTRA® infusion.
- **For Cycle 3 and Cycle 4 doses**, your healthcare provider will watch you for **3 to 4 hours** after the IMDELLTRA® infusion.
- **For Cycle 5 and later doses**, your healthcare provider will watch you for **2 hours** after the IMDELLTRA® infusion.

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with IMDELLTRA® and treat you as needed. You may be hospitalized if you develop signs or symptoms of CRS or neurologic problems during treatment with IMDELLTRA®. Your healthcare provider may temporarily stop or completely stop your treatment with IMDELLTRA® if you develop CRS or neurologic problems.

**Before receiving IMDELLTRA®, tell your healthcare provider about all of your medical conditions, including if you:**

- have an infection
- are pregnant or plan to become pregnant. IMDELLTRA® may harm your unborn baby.

**Females who are able to become pregnant:**

- Your healthcare provider should do a pregnancy test before you start treatment with IMDELLTRA®.

- You should use an effective form of birth control (contraception) during treatment with IMDELLTRA®, and for 2 months after the last dose of IMDELLTRA®.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with IMDELLTRA®.
- are breastfeeding or plan to breastfeed. It is not known if IMDELLTRA® passes into your breast milk. Do not breastfeed during treatment with IMDELLTRA® and for 2 months after the last dose of IMDELLTRA®.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**What should I avoid while receiving IMDELLTRA®?**

**Do not** drive, operate heavy or potentially dangerous machinery or do other dangerous activities, including work-related activities, during treatment with IMDELLTRA® if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of neurologic problems.

**What are the possible side effects of IMDELLTRA®?**

**IMDELLTRA® can cause serious side effects, including:**

- **Low blood cell counts (cytopenia).**

Decreased blood cell counts can be severe and may include the following:

- low white blood cell counts (neutropenia). Low white blood cells can increase your risk for infection.
- low red blood cell counts (anemia). Low red blood cells can cause tiredness and shortness of breath.
- low platelet counts (thrombocytopenia). Low platelet counts can cause bruising or bleeding problems.

- **Infections.** IMDELLTRA® can cause serious infections that can be life-threatening and cause death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment with IMDELLTRA®. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with IMDELLTRA®, including: fever of 100.4°F (38°C) or higher; painful rash, cough, sore throat or runny nose, chest pain, pain during urination, tiredness, feeling weak or generally unwell, shortness of breath, yeast infections in the mouth or other areas.

- **Liver problems.** IMDELLTRA® can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Tell your healthcare provider right away if you develop any signs or symptoms of liver problems, including: tiredness, dark urine, loss of appetite, yellowing of your skin or the white part of your eyes, pain in your right upper stomach-area (abdomen).

- **Allergic reactions.** IMDELLTRA® can cause allergic reactions that can be severe. Go to the nearest emergency room or get medical help right away if you develop any signs or symptoms of a severe allergic reaction during treatment with IMDELLTRA®, including: shortness of breath or trouble breathing, coughing, pain or tightness in your chest and back, feeling lightheaded or dizzy, wheezing, rash.

Your healthcare provider will do bloodwork before you start and during treatment with IMDELLTRA®. Your healthcare provider will monitor you for signs or symptoms of these serious side effects during treatment and may temporarily or completely stop treatment with IMDELLTRA® if you develop certain serious side effects.

- **The most common side effects of IMDELLTRA® also include:**

- tiredness
- decreased appetite
- a bad or metallic taste in your mouth
- fever
- muscle or bone pain
- constipation
- nausea

These are not all the possible side effects of IMDELLTRA®.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Please see IMDELLTRA® full [Prescribing Information](#), including **BOXED WARNINGS** and [Medication Guide](#).**

**Reference:** IMDELLTRA® (tarlatamab-dlle) prescribing information, Amgen.



For more information, visit:

**IMDELLTRA.com**

Please see IMDELLTRA® full [Prescribing Information](#), including **BOXED WARNINGS** and [Medication Guide](#).



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**IMDELLTRA®**  
(tarlatamab-dlle) for injection  
1 mg & 10 mg single-use vials