PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr IMDELLTRA™

tarlatamab for injection

Read this carefully before you start taking **Imdelltra** and each time you get an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Imdelltra**.

Serious Warnings and Precautions

Imdelltra can cause serious side effects that can be severe or life-threatening, including:

- A serious side effect called cytokine release syndrome (CRS), which can be severe or life-threatening, may occur. Symptoms usually include fever (38°C or higher) and chills. Other symptoms of CRS may include shortness of breath, confusion, restlessness, trouble breathing, fast or irregular heartbeat, palpitations, dizziness, headache, nausea and vomiting.
- Serious or life-threatening neurologic problems may occur after taking Imdelltra. Symptoms may include trouble speaking or writing, memory loss, personality changes (encephalopathy), confusion, feeling disoriented or having difficulty thinking clearly (delirium), seizure, loss of balance or coordination (ataxia), weakness or numbness of arms and legs, shakiness of your hands or limbs (tremor), and headache. Some of these may be signs of a serious immune reaction called 'immune effector cell associated neurotoxicity syndrome' (ICANS). These effects can occur days or weeks after you receive the injection and may be subtle at first.

Your healthcare professional will monitor for signs and symptoms of CRS and neurological problems during treatment with Imdelltra. Call your doctor or get emergency help right away if you develop any of these signs and symptoms of CRS or neurologic problems at any time during your treatment with Imdelltra.

What is Imdelltra used for?

Imdelltra is a cancer medicine that contains the active substance "tarlatamab".

"For the following indication Imdelltra has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional."

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 at least two prior treatments including chemotherapy that includes platinum, and it did not work or is no longer working.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does Imdelltra work?

Imdelltra is a bispecific molecule that binds to DLL3 on the surface of small cell lung tumour cells and also to the surface of T cells (a type of white blood cell). Imdelltra works by attaching to these cells and bringing them together, to help your immune system target the small cell lung cancer cells.

If you have any questions about how Imdelltra works or why this medicine has been prescribed for you, ask your healthcare provider.

What are the ingredients in Imdelltra?

Medicinal ingredients: tarlatamab

Non-medicinal ingredients: L-glutamic acid, Polysorbate 80, Sodium hydroxide, Sucrose

Ingredients in the IV Solution Stabilizer (IVSS), a liquid that will be used by the healthcare professional to prepare your dose of Imdelltra: citric acid monohydrate, lysine hydrochloride, polysorbate 80, sodium hydroxide and water for injection.

Imdelltra comes in the following dosage forms:

Lyophilized powder for solution for intravenous infusion, 1 mg and 10 mg per vial.

Each package contains three vials: one vial of Imdelltra containing 1 or 10 mg powder and two vials of 7 mL IVSS.

Do not use Imdelltra if:

- you are allergic to tarlatamab or to any of the ingredients of Imdelltra. If you are not sure if you allergic, talk to your doctor or nurse before you are given Imdelltra.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Imdelltra. Talk about any health conditions or problems you may have, including if you:

- have an infection.
- have or had problems with your nervous system.
- have or had any liver or kidney problems.
- are pregnant or plan to get pregnant.
- are breast-feeding or plan to breast-feed.
- had a recent vaccination or are going to have a vaccination. You should not receive live vaccines from 4 weeks before until 6 weeks after you are treated with Imdelltra.

Imdelltra can cause serious side effects that can be severe or life-threatening.

These side effects include cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS).

Call your doctor or get emergency help right away if you get any of the symptoms listed above in the Serious Warning and Precautions Box. Your doctor may give you medicine to treat your side effects. Your healthcare provider will check for these problems during treatment with Imdelltra.

Other warnings you should know about:

- **Pregnancy, contraception, breastfeeding and fertility**

  The effects of Imdelltra in pregnant women are not known.

  - Imdelltra may harm your unborn baby. Pregnancy must be ruled out before treatment with Imdelltra. Tell your healthcare provider if you are pregnant, think you are pregnant, or if you are planning to become pregnant.
  - Tell your healthcare provider immediately if you become pregnant during treatment with Imdelltra. Women who are able to become pregnant must use birth control during treatment with Imdelltra and for 2 months after your last dose. Talk to your healthcare provider about effective methods of birth control.
  - It is not known whether Imdelltra passes into breast milk. Do not breast-feed during treatment with Imdelltra and for at least 2 months after your last dose.
  - The effects of Imdelltra on male and female fertility are not known.

- **Driving and Using Machines**
  - Do not drive, operate heavy or potentially dangerous machinery and engage in hazardous occupations or activities following Imdelltra infusion in case you develop neurological symptoms (such as dizziness, seizures, sleepiness, confusion, etc.) until you feel better.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Imdelltra:

- It is not known which medications interact with Imdelltra.

How to take Imdelltra:

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

Imdelltra will be given on the following schedule: Day 1, Day 8, Day 15 and then every 2 weeks thereafter.

On Cycle Day 1 and Cycle 1 Day 8, you will receive medication (such as corticosteroids) one hour before receiving Imdelltra to help lower the chance of side effects. This will be given to you by IV infusion into your vein.

On Cycle Day 1, Cycle 1 Day 8 and Cycle 1 Day 15 you will receive fluids by IV infusion into your vein after Imdelltra infusion to lower the chance of side effects.

You may also receive these treatments for later doses of Imdelltra based on any symptoms or side effects you have.

Usual dose:

The starting dose of Imdelltra is 1 mg on Day 1 followed by 10 mg on Days 8, 15, and then every 2 weeks thereafter.

Your healthcare provider will determine how long you should stay on Imdelltra.

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

Your healthcare provider will regularly check your blood counts as the number of blood cells and other blood components may decrease.

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 of Cycle 1 doses, your healthcare provider will monitor you for 24 hours from the start of the Imdelltra infusion in an appropriate healthcare setting. You should remain within 1 hour of an appropriate healthcare setting for 48 hours from the start of your Imdelltra infusion on Cycle 1 Day 1, and Cycle 1 Day 8 **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 4 hours after the Imdelltra infusion.

For Cycle 5 and later doses, your healthcare provider will watch you for at least 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, as well as other side effects, 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, neurologic problems, or any other side effects that are severe.

Overdose:

If you think you, or a person you are caring for, have taken too much Imdelltra, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important to go to all of your appointments. If you miss any appointments, call your healthcare professional as soon as possible to reschedule. It is important for you to be monitored closely for side effects during treatment with Imdelltra.

What are possible side effects from using Imdelltra?

These are not all the possible side effects you may have when taking Imdelltra. If you experience any side effects not listed here, tell your healthcare professional.

Very common (may affect more than 1 in 10 people):

- decreased levels of red blood cells (anemia)
- constipation
- diarrhea
- vomiting
- 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 of nervous system (neurotoxicity)
- shakiness of hands and limbs (tremor)
- confusion (confusional state)
- feeling disoriented (delirium)

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Cytokine release syndrome: fever, shortness of breath, confusion, restlessness, trouble breathing, fast or irregular heartbeat, palpitations, dizziness, headache, chills, nausea, vomiting		X	
Infections: fever of 100.4°F (38°C) or higher, cough, chest pain, tiredness, shortness of breath, painful rash, sore throat, pain during urination, feeling weak or generally unwell		X	

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON			
Neurological problems, including Immune effector cell-associated neurotoxicity syndrome: trouble speaking or writing, memory loss, personality changes (encephalopathy), confusion, feeling disoriented or having difficulty thinking clearly (delirium), seizure, loss of balance or coordination (ataxia), weakness or numbness of arms and legs, shakiness of your hands or limbs (tremor), headache		X	
Cytopenia (low white blood cell counts, low red blood cell counts and low platelet counts): chills or shivering, feel warm, high body temperature		X	
Tumour lysis syndrome: complications occurring after treatment of a fast-growing cancer leading to a change in certain chemicals in the blood (increase potassium, uric acid, and phosphate and decreased blood levels of calcium), which may cause damage to organs, including the kidneys, heart, and liver		X	
Liver problems: 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		X	
VERY RARE			
Allergic reactions: shortness of breath or trouble breathing, pain or tightness in your chest and back, wheezing, coughing, feeling lightheaded or dizzy, rash		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Imdelltra will be stored and managed by healthcare professionals. The information below on how to store Imdelltra is meant for your healthcare professional.

Unopened vials:

Store refrigerated (2°C to 8°C).

Keep in the original carton to protect from light. Do NOT freeze.

Prepared solution:

Prepared Imdelltra solution in the IV bag can be stored refrigerated (2°C to 8°C) for up to 7 days, or at room temperature (20°C to 25°C) for up to 8 hours.

Keep out of reach and sight of children.

If you want more information about Imdelltra:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website: www.amgen.ca, or by calling 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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