

**PART III: CONSUMER INFORMATION**

**PrTREANDA®**  
**Bendamustine hydrochloride for injection**  
**25 mg and 100 mg per vial**

**This leaflet is part III of a three-part "Product Monograph" published when TREANDA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TREANDA. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**

TREANDA is a medicine which is used for the treatment of the following types of cancer:

- Relapsed indolent B-cell non-Hodgkin lymphoma (NHL), which has not responded during or following treatment with a rituximab regimen;
- Previously untreated chronic lymphocytic leukemia (CLL) (cancer of the white blood cells).

**What it does:**

TREANDA has been shown to cause cell death. The exact way in which TREANDA kills cells is not completely understood.

**When it should not be used:**

Do not use TREANDA if you are allergic to the active substance, bendamustine hydrochloride, or mannitol.

**What the medicinal ingredient is:**

Bendamustine hydrochloride

**What the non-medicinal ingredients are:**

Mannitol

**What dosage forms it comes in:**

TREANDA is available as powder for injection in a vial that contains 25 mg or 100 mg of bendamustine hydrochloride.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

TREANDA should be prescribed and managed by a doctor experienced in the use of cancer drug.

TREANDA should not be used in patients with serious infections.

Possible serious side effects with TREANDA include:

- serious infection
- having other types of cancers
- decreased production of blood cells (myelosuppression)
- serious heart problems
- serious skin reactions

**BEFORE you receive TREANDA talk to your doctor or pharmacist if:**

- You have a known allergy to bendamustine or mannitol
- You have low blood cell count (white blood cells, platelets, and red blood cells)
- You have any heart problems or high blood pressure
- You have any infection
- You have any skin problem
- You are pregnant or are planning to become pregnant
- You are breast-feeding or plan to breast-feed
- You have kidney or liver problem

TREANDA can harm an unborn baby. Female and male patients should use an effective contraception 2 weeks before receiving TREANDA and until at least 4 weeks after the last dose. If pregnancy is suspected, talk to your doctor immediately.

TREANDA may also affect men who wish to father a child.

TREANDA has not been shown to be effective in patients under 18 years of age.

TREANDA may also cause:

- Extravasation (the leakage of drug from the vein into the surrounding tissue)
- Tumor lysis syndrome (caused by death of cancer cells)
- Infusion reactions and anaphylaxis, symptoms include swelling of the face, lips or tongue, difficulty breathing, rash, or fainting.

**INTERACTIONS WITH THIS MEDICATION**

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription.

**PROPER USE OF THIS MEDICATION**

TREANDA is to be given into the vein (intravenous) as an infusion.

**Usual dose:**

**Relapsed indolent non-Hodgkin lymphoma**

120 mg/m<sup>2</sup> body surface area given into the vein as an infusion over 60 minutes, on day 1 and 2 of a 21-day cycle, up to 8 cycles.

**Chronic lymphocytic leukemia**

100 mg/m<sup>2</sup> body surface area given into the vein as an infusion over 30 minutes, on day 1 and 2 of 28-day cycle, up to 6 cycles.

**Missed Dose:**

TREANDA should be given on a fixed schedule. If you miss an appointment, call your doctor for instructions.

**Overdose:**

In case of drug overdose, contact your doctor, or your healthcare provider, or a local poison control centre, or go to the emergency room of the nearest hospital.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The most common blood-related side effects with TREANDA are: low levels of some types of white blood cells (neutrophils, leucocytes), platelets or red blood cells.

The most common non-blood-related side effects with TREANDA are nausea, fatigue, diarrhea, vomiting, fever, constipation.

The most common severe side effects: fatigue, fever associated with low level of neutrophils, pneumonia, potassium deficiency, diarrhea, dehydration, fever, infection, high blood level of uric acid, rash, high blood pressure.

Other important serious side effects: kidney failure, heart failure, myocardial infarction, allergic reaction, skin reactions, lung scarring that can interfere with breathing, decreased production of blood cells by the bone marrow and liver problems.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor		Seek immediate emergency medical attention
	Only if severe	In all cases	
<b>Common</b>	<b>Nausea and vomiting</b>	√	
	<b>New fever or temperature higher than 38°C</b>		√
	<b>Severe or worsening rash or itching</b>		√
	<b>Myelosuppression:</b> Shortness of breath, significant fatigue, bleeding, fever or other signs of infection		√
<b>Uncommon</b>	<b>Allergic reaction:</b> Skin reactions such as rash or itching, facial swelling, or difficulty breathing during or soon after infusion		√
	<b>Tumor Lysis Syndrome:</b> Lack of urination, severe muscle weakness, heart rhythm disturbances and seizures		√
	<b>Diarrhea</b>	√	
<b>Rare</b>	<b>Severe Skin Reactions:</b> Severe or worsening itching, intense redness, formation of hives, blistering or ulceration associated with either fever, joint pain, or a general unwell feeling		√
	<b>Heart Failure:</b> Chest pain, dizziness, fatigue, rapid breathing, shortness of breath, swelling of the feet or legs.		√

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor		Seek immediate emergency medical attention
	Only if severe	In all cases	
<b>Rare</b> <b>Heart Attack:</b> Pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, lightheadedness, clammy skin, sweating, indigestion, anxiety.		√	√
		√	√
<b>Liver Injury:</b> Pain in the right abdomen, fever, fatigue, weakness, loss of appetite, jaundice, yellow color in the eyes, dark urine.		√	√

*This is not a complete list of serious side effects. For any unexpected effects while taking TREANDA, contact your doctor or pharmacist.*

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701D  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

For questions or concerns and to find the full product monograph prepared for healthcare professionals, go to <http://www.tevacanadainnovation.ca> or contact the sponsor, Teva Canada Innovation at 1-833-662-5644.

This leaflet was prepared by Teva Canada Innovation.

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