Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

(Ad-SET-riss)

ADCETRIS®

brentuximab vedotin for injection

This patient medication information is written for the person who will be taking **ADCETRIS**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ADCETRIS**, talk to a healthcare professional.

Serious warnings and precautions box

In patients treated with ADCETRIS, the following serious side effects have occurred and were fatal in some cases:

- Brain infection causing a serious and potentially fatal condition called progressive multifocal leukoencephalopathy (PML)
- Severe skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis
- Infections
- Pancreatitis (inflammation of the pancreas)
- Stomach or intestine (gastrointestinal) problems
- Lung problems

See below for signs and symptoms of these serious side effects. Immediately report to your doctor if you notice any of the described symptoms.

What ADCETRIS is used for:

ADCETRIS is used to treat patients with:

- Hodgkin lymphoma (HL) that is advanced stage and has not already been treated, when used in combination with a chemotherapy regimen of doxorubicin, vinblastine and dacarbazine.
- Hodgkin lymphoma (HL) at increased risk of continuing or returning, as additional treatment after an autologous stem cell transplant (ASCT).
- Hodgkin lymphoma (HL) that has come back after a stem cell transplant or after two types of chemotherapy if you cannot receive a stem cell transplant.
- Systemic Anaplastic Large Cell Lymphoma (sALCL), CD30-expressing Peripheral T-cell Lymphoma-not otherwise specified (PTCL-NOS), or CD30-expressing Angioimmunoblastic T-cell Lymphoma (AITL),

that has not already been treated, used in combination with cyclophosphamide, doxorubicin, and prednisone.

- Systemic anaplastic large cell lymphoma (sALCL) that comes back after treatment with chemotherapy.
- Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have had prior systemic therapy.

How ADCETRIS works:

ADCETRIS contains brentuximab vedotin, which is made up of two types of medicine that are attached to each other. One part belongs to a group of medicines called monoclonal antibodies and the other belongs to a group of medicines called anti-mitotics. The monoclonal antibody part allows the drug to find the cancer cell in the body; the anti-mitotic part kills the cancer cell once it is found.

ADCETRIS attaches to a molecule called CD30 that is present on the surface of HL and sALCL cancer cells, but not usually on healthy cells. ADCETRIS then enters the cancer cells and kills them by releasing an anti-mitotic that is toxic to the cancer cells. Even though ADCETRIS usually attaches to cancer cells, and not healthy cells, it can still cause side effects. These should be discussed with your doctor.

The ingredients in ADCETRIS are:

Medicinal ingredients: brentuximab vedotin

Non-medicinal ingredients: polysorbate 80, sodium citrate, trehalose

ADCETRIS comes in the following dosage forms:

ADCETRIS comes in a single-use vial containing 50 mg of brentuximab vedotin for injection.

Do not use ADCETRIS if:

- You have a known allergy to the medicinal or non-medicinal ingredients.
- You are currently taking another drug called bleomycin. Bleomycin must be stopped before starting ADCETRIS.
- You have or have had progressive multifocal leukoencephalopathy (PML).

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

- take a medicine to treat or prevent fungal infections;
- are taking antibiotics for tuberculosis;
- have or have had a liver or kidney disease;
- might be pregnant or are trying to become pregnant;
- are breast feeding;
- are allergic to the ingredients in ADCETRIS.

Other warnings you should know about:

- Women who may become pregnant should use at least 2 reliable methods of birth control during and for 6 months after treatment with ADCETRIS. Immediately report to your doctor if you become pregnant while receiving ADCETRIS.
- Do not breastfeed while you are receiving ADCETRIS. It is not known if the drug can get into breast milk, and therefore, into the baby.
- Men should use an appropriate method of barrier contraception during and for 6 months after treatment with ADCETRIS.

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 ADCETRIS:

- Some medicines and foods (like grapefruit juice) may change the amount of the anti-mitotic in your body.

How to take ADCETRIS:

ADCETRIS is given as an intravenous infusion over 30 minutes**.**

Usual dose:

For patients with

- HL that is advanced stage and has not been previously treated, given in combination with a chemotherapy regimen of doxorubicin, vinblastine and dacarbazine.

The usual dose is 1.2 mg/kg given at 2-week intervals for up to 12 doses. If you have mild liver disease, the dose may be 0.9 mg/kg. If you have serious liver or serious kidney disease, ADCETRIS use should be avoided. If you weigh more than 100 kg, your dose will be calculated as if your weight was 100 kg. While taking ADCETRIS, you may also receive medicine that will help to reduce the chance of infection. Treatment with ADCETRIS will be stopped if your disease gets worse or if you experience unacceptable side effects.

For patients with

- HL at increased risk of continuing or returning, as additional treatment after an autologous stem cell transplant (ASCT).
- HL that has come back after a stem cell transplant or after two types of chemotherapy if you cannot receive a stem cell transplant.
- sALCL that has come back after treatment with chemotherapy.
- pcALCL or with certain types of MF after at least one systemic therapy

The usual dose is 1.8 mg/kg given at 3-week intervals. If you have mild liver disease, the dose may be 1.2 mg/kg. If you have more serious liver or serious kidney disease, ADCETRIS use should be avoided. If you weigh more than 100 kg, your dose will be calculated as if your weight is 100 kg. You will receive ADCETRIS at 3-week intervals. Treatment with ADCETRIS will be stopped if your disease gets worse, if you experience unacceptable side effects, or if you reach the recommended number of doses.

If you are receiving ADCETRIS after an ASCT, your treatment should begin within 4–6 weeks after ASCT or recovery from ASCT. Treatment with ADCETRIS will continue for up to 16 doses or until your disease gets worse or if you experience unacceptable side effects.

If you are a patient with certain types of PTCL that has not already been treated, you will receive ADCETRIS in combination with cyclophosphamide, doxorubicin, and prednisone.

Overdose:

It is unlikely that you will receive too much ADCETRIS as you will be closely monitored by healthcare professionals during your infusion.

If you think you, or a person you are caring for, have taken too much ADCETRIS, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss your appointment to receive ADCETRIS, you should make every effort to receive the missed dose as soon as possible. Doses should not be given less than 3 weeks apart.

Possible side effects from using ADCETRIS:

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

Very common (≥ 10%) side effects associated with the use of ADCETRIS include:

- Nausea
- Vomiting
- Fatigue
- Diarrhea
- Hair loss
- Rash
- Itching
- Fever
- Swelling in limbs
- Difficulty Sleeping
- Joint and muscle pain
- Shortness of breath
- Low red blood cell counts
- Low white blood cell counts.
- Low platelet counts
- Constipation
- Decreased appetite
- Headache
- Dizziness
- Cough
- Low blood potassium
- Decreased weight

These side effects may occur during and after treatment with ADCETRIS.

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Very common (≥ 10%)		
Nerve damage: burning sensation, pain, numbness and tingling (feeling of pins and needles) of hands and/or feet, weakness, difficulty walking		X
Infection: fever of ≥38°C or greater, chills, cough, sore throat, or pain on urination		X
Infusion reaction: fever, wheezing or breathing problems, chills, nausea, cough, itching, rash, within 2 days after your dose	X	
Liver damage: yellow coloration to the skin or the whites of the eyes		X
Common (≥ 1% to <10%)		
Stomach/ intestine (gastrointestinal) problems: new or worsening severe abdominal pain, severe nausea, vomiting, or severe diarrhea		X
Lung problems: cough and shortness of breath	X	
High blood sugar: frequent need to urinate, increased thirst, blurred vision	X	
Uncommon (≥ 0.1% to <1%)		
Pancreatitis (inflammation of the pancreas): symptoms such as abdominal pain, fever, nausea, vomiting		X
Tumor lysis syndrome: nausea, vomiting, edema (swelling), shortness of breath, heart rhythm disturbance, and sudden kidney failure		X
Rare (<0.1%)		
Progressive multifocal leukoencephalopathy: changes in mood or usual behavior, confusion, difficulty with thinking, memory loss, changes in vision or speech, decreased control or sensation in one arm or leg, loss of balance, changes in way of walking. Inform anyone close to you about your treatment since they may notice symptoms of which you are not aware.		X
Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis): unexplained widespread skin pain, blisters on your skin and mucous membranes, hives, tongue swelling, a red or purple skin rash that spreads, or unexplained shedding of your skin		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 (canada.ca/drug-device-reporting) 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:

Store ADCETRIS at 2–8°C in the original carton. Protect from light.

Keep out of reach and sight of children.

If you want more information about ADCETRIS:

- 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 Drug Product Database website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.seagen.com, or by calling 1-833-473-2436.

This leaflet was prepared by Seagen Inc.

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