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## Brentuximab Vedotin Injection

pronounced as (bren tux' i mab ve doe' tin)

### IMPORTANT WARNING:

Receiving brentuximab vedotin injection may increase the risk that you will develop progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability). Tell your doctor if you have or have ever had a condition that affects your immune system. Tell your doctor and pharmacist if you are taking any medications that suppress the immune system. If you experience any of the following symptoms, stop receiving brentuximab vedotin injection and call your doctor immediately: decreased strength or weakness on one side of the body; difficulty walking; loss of coordination; headache; confusion; difficulty thinking clearly; memory loss; changes in mood or usual behavior; difficulty speaking; or vision changes.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain tests to check your body's response to brentuximab vedotin injection.

Talk to your doctor about the risks of receiving brentuximab vedotin injection.

### Why is this medication prescribed?

#### Brentuximab vedotin injection is used

- in combination with other chemotherapy medications to treat Hodgkin's lymphoma (Hodgkin's disease) in those who have not previously received treatment,
- to treat Hodgkin's lymphoma in those who are at risk for their disease to become worse or come back after a stem cell transplant (procedure that replaces diseased bone marrow with healthy bone marrow),
- to treat Hodgkin's lymphoma in those who did not respond to a stem cell transplant (procedure that replaces diseased bone marrow with healthy bone marrow) or at least two treatment periods of chemotherapy,
- in combination with other chemotherapy medications to treat anaplastic large cell lymphoma (sALCL; a type of non-Hodgkin lymphoma) and other certain types of peripheral T-cell lymphomas (PTCL; a type of non-Hodgkin lymphoma) in those who have not previously received treatment,

- to treat systemic sALCL in those who did not respond to another treatment period of chemotherapy, ,
- to treat a certain type of primary cutaneous anaplastic large cell lymphoma (pcALCL; a type of non-Hodgkin's lymphoma) in people who have previously received another treatment.

Brentuximab vedotin injection is in a class of medications called antibody-drug conjugates. It works by killing cancer cells.

## How should this medicine be used?

Brentuximab vedotin injection comes as a powder to be mixed with fluid and injected over 30 minutes intravenously (into a vein) by a doctor or nurse in a medical office or hospital. When brentuximab vedotin is given to treat Hodgkin's lymphoma, sALCL, or PTCL, it is usually injected once every 3 weeks for as long as your doctor recommends that you receive treatment. When brentuximab vedotin is used in combination with chemotherapy to treat Hodgkin lymphoma as a first treatment, it is usually injected once every 2 weeks for as long as your doctor recommends that you receive treatment.

Brentuximab vedotin injection may cause serious allergic reactions, which usually occur during the infusion of the medication or within 24 hours of receiving a dose. You may receive certain medications before your infusion to prevent an allergic reaction if you had a reaction with previous treatment. Your doctor will watch you carefully while you are receiving brentuximab vedotin. If you experience any of the following symptoms, tell your doctor immediately: fever, chills, rash, hives, itching, or difficulty breathing.

Your doctor may need to delay your treatment, adjust your dose, or stop your treatment if you experience certain side effects. Be sure to tell your doctor how you are feeling during your treatment with brentuximab vedotin injection.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before receiving brentuximab vedotin injection,

- tell your doctor and pharmacist if you are allergic to brentuximab vedotin, any other medications, or any of the ingredients in brentuximab vedotin injection. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are receiving bleomycin. Your doctor will probably tell you not to use brentuximab vedotin injection if you are receiving this medication.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: clarithromycin (Biaxin, in PrevPac), indinavir (Crixivan), itraconazole (Sporanox), ketoconazole, nefazodone, nelfinavir (Viracept), rifampin (Rifadin, Rimactane, in Rifamate, in Rifater), and ritonavir (Norvir, in Kaletra). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had liver or kidney disease.

- tell your doctor if you are pregnant or plan to become pregnant. If you are a woman who is able to become pregnant, you must take a pregnancy test before starting treatment and use effective birth control during your treatment and for 6 months after your final dose. If you are male with a female partner who is pregnant or could become pregnant, you must use effective birth control during your treatment and for 6 months after your final dose. Talk to your doctor about birth control methods that you can use. If you or your partner become pregnant while receiving brentuximab vedotin injection, call your doctor immediately. Brentuximab vedotin injection may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed while you are receiving brentuximab vedotin injection.
- you should know that this medication may decrease fertility in men. Talk to your doctor about the risks of receiving brentuximab vedotin injection.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What side effects can this medication cause?

**Brentuximab vedotin injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- constipation
- mouth sores
- decreased appetite
- weight loss
- tiredness
- dizziness
- weakness
- difficulty falling asleep or staying asleep
- anxiety
- dry skin
- hair loss
- night sweats
- joint, bone, muscle, back, arm, or leg pain
- muscle spasms

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:**

- unusual bleeding or bruising
- numbness, burning, or tingling in the hands, arms, feet, or legs

- muscle weakness
- peeling or blistering skin
- hives
- rash
- itching
- nausea
- vomiting
- diarrhea
- cough or shortness of breath
- decreased urination
- swelling of the hands, feet, ankles, or lower legs
- difficult, painful, or frequent urination
- fever, chills, cough, or other signs of infection
- ongoing pain that begins in the stomach area but may spread to the back
- pale skin
- yellowing of the skin or eyes
- pain or discomfort in the right upper stomach area
- dark urine
- clay-colored bowel movements
- stomach pain
- unusual bleeding or bruising
- black and tarry stools
- red blood in stools

Brentuximab vedotin injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## **In case of emergency/overdose**

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- fever, chills, cough, or other signs of infection

## What other information should I know?

Ask your pharmacist any questions you have about brentuximab vedotin injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Adcetris<sup>®</sup>

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