

ADCETRIS[®] ▼

brentuximab vedotin

Your treatment and what to expect from it

Information for people who have been prescribed ADCETRIS (brentuximab vedotin) for Hodgkin lymphoma, systemic anaplastic large cell lymphoma or cutaneous T-cell lymphoma.

This booklet does not replace your healthcare professional's advice. Always ask your doctor, nurse or pharmacist any questions you might have about your treatment or disease.

What is brentuximab vedotin?

Brentuximab vedotin is an anti-cancer agent intended to kill cancer cells. The reason you are receiving brentuximab vedotin depends on the type of cancer you have.

ADCETRIS has received a conditional marketing authorisation in Europe. A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact additional data are still required. The European regulatory agency will review new information on ADCETRIS at least every year and the summary of product characteristics will be updated as necessary.

Why am I being given brentuximab vedotin?

Hodgkin lymphoma (HL)

Brentuximab vedotin is used to treat adults with HL that has:

- Come back after, or not responded to, a stem cell transplant
- or**
- Come back after, or not responded to, at least two previous anti-cancer therapies,

when

additional combination anti-cancer treatments or a stem-cell transplant are not treatment options

Brentuximab vedotin is also used to lower the likelihood of HL coming back after a stem cell transplant in people with certain risk factors.

Systemic anaplastic large cell lymphoma (sALCL)

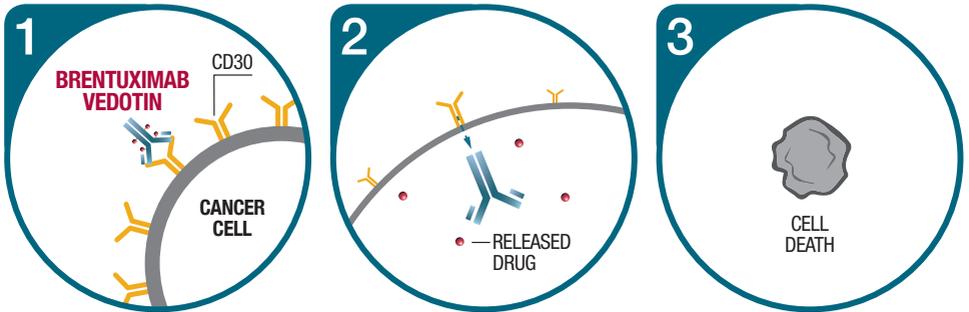
Brentuximab vedotin is used to treat adult patients with sALCL that has come back after, or not responded to previous anti-cancer treatment.

Cutaneous T-cell lymphoma (CTCL)

Brentuximab vedotin is used to treat adult patients with CTCL in people who have previously received at least one anti-cancer medicine that travels through the bloodstream.

How does brentuximab vedotin work?

Brentuximab vedotin recognises and only attacks a specific target (CD30) that is found on the surface of some types of cancer cells and delivers an anti-cancer (cytotoxic) agent to these cancer cells. Once inside the cancer cells, the anti-cancer agent stops the cancer cell from dividing which eventually kills it.



What is the evidence for brentuximab vedotin?

Brentuximab vedotin has been approved for use based on results from clinical trials involving people with Hodgkin lymphoma, systemic anaplastic large cell lymphoma or cutaneous T-cell lymphoma that had not responded to, or had come back after, previous treatments. More information on the results from these clinical trials can be found at www.adcetris.co.uk/patient.

Visit www.adcetris.co.uk/patient or speak to your nurse or doctor if you would like more information.

Important information before you are given brentuximab vedotin

Progressive multifocal leukoencephalopathy (PML)

You should be aware of the signs and symptoms of a condition called PML. PML is a rare (affects less than 1 in 100 people) but serious and potentially fatal brain condition that has been reported in a small number of patients who received brentuximab vedotin after previously receiving multiple rounds of cancer treatment.

PML symptoms include confusion, trouble thinking, memory loss, blurred or loss of vision, decreased strength, decreased control or sensation in arms or legs, a change in the way of walking or loss of balance.



If you have experienced any of these symptoms prior to treatment with brentuximab vedotin, tell your doctor immediately about any changes in these symptoms.

You should inform your partner or caregivers about your treatment, since they may notice symptoms that you are not aware of.



Other medicines

Tell your doctor if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes herbal medicines and other medicines you can obtain without a prescription.

You should not be given brentuximab vedotin if you are currently receiving another chemotherapy drug called **bleomycin**.



Pregnancy, breast-feeding, male and female fertility

You should not use brentuximab vedotin if you are pregnant unless you and your doctor decide that the benefit to you outweighs the potential risk to the unborn baby.



It is important to tell your doctor before and during treatment if you are pregnant, think you may be pregnant, or are planning to get pregnant.

If you are breast-feeding, you should discuss with your doctor whether you should receive this medicine.

You and your partner should use two methods of effective contraception during your treatment with brentuximab vedotin.

Women must continue using contraception for 6 months following the last dose of brentuximab vedotin.

Men are advised to have sperm samples frozen and stored before treatment and to not father a child during treatment and for up to 6 months following the last dose.



Driving and using machines

Your treatment may influence your ability to drive or operate machines. If you feel unwell during treatment then do not drive or operate machines.

How will I be given brentuximab vedotin?

Brentuximab vedotin is given as a drip (infusion) in hospital



- Brentuximab vedotin is given to you by your doctor or nurse as an infusion into a vein (intravenously)
- The infusion is usually an outpatient procedure and takes approximately 30 minutes. You will be monitored during and after the procedure
- Your care team will schedule your appointments with you

Brentuximab vedotin is usually given once every 3 weeks



- Your response to brentuximab vedotin will be monitored during and after treatment
- Depending on how you respond, treatment can continue for up to approximately one year

Infusion-related reactions

Some people (more than 1 in 10) experience reactions to the infusion such as:



Rash



Shortness of breath



Difficulty breathing



Cough



A tight chest



Fever



Back pain



Chills



Headache



Feeling sick (nausea) or being sick (vomiting)

In general, these types of reactions occur within minutes to several hours following completion of the infusion. However, they may develop more than several hours after completion of the infusion, but this is uncommon. It is important you tell your doctor if you have previously experienced infusion reactions **before** you are given this medicine as they can be serious or even fatal.

If you develop infusion reactions your doctor may stop giving you this medicine and start support treatment. If your infusion is restarted, your doctor may increase the time over which your infusion is given so that you may be able to tolerate it better.

If you have any questions on the use of brentuximab vedotin, ask the doctor or nurse who is giving you the infusion.

What should I look out for during treatment that I should I tell my doctor about?

Tell your doctor

There are some side effects that are really important to look out for. Let your doctor know straight away if you have any of the following side effects:



Changes in feeling or sensitivity e.g. numbness or tingling in the hands or feet (these are symptoms of a condition known as peripheral neuropathy)



Symptoms of inflammation of the pancreas (pancreatitis) such as severe and persistent stomach pain, with or without nausea and vomiting



Feeling tired, frequently needing to urinate, increased thirst, increased appetite with unintended weight loss and irritability, which may be signs of hyperglycaemia (high blood sugar)



Unusual bleeding or bruising under the skin, longer than usual bleeding after your blood has been drawn or bleeding from your gums, which may be signs of thrombocytopenia (low platelets)



Dizziness, reduced need to urinate, confusion, vomiting, nausea, swelling, shortness of breath or heart rhythm disturbances, which may be signs of tumour lysis syndrome



Headaches, dizziness or pale complexion, which may be signs of anaemia



Flu like symptoms followed by a painful red or purplish blistering rash that spreads



Constipation



Shortness of breath or cough



Vomiting



Symptoms of progressive multifocal leukoencephalopathy (see page 4)



Chills or shivering



Feeling of weakness



Diarrhoea

Will I get any side effects from brentuximab vedotin?

Like all medicines, brentuximab vedotin may cause side effects, although not everybody gets them, and each person will experience them differently.

The most common side effects people experience from brentuximab vedotin include:

Affect more than 1 in 10 people (very common)

- Changes in feeling or sensitivity e.g. numbness or tingling in the hands or feet (these are symptoms of a condition known as peripheral neuropathy)
- Decreased level of cells in your blood that help you fight infections (white blood cells)
- Infection
- Diarrhoea, nausea, vomiting
- Itching
- Muscle pain
- Fatigue, fever, infusion-related reactions
- Shortness of breath or cough
- Upper respiratory tract infection
- Feeling of weakness
- Constipation
- Abdominal pain
- Joint pain or painful, swollen joints
- Weight loss

Affect more than 1 in 100, but less than 1 in 10 people (common)

- Pneumonia
- Decreased level of blood cell fragments that help clot your blood (platelets)
- Dizziness
- Blisters which may crust or scab
- Increased level of blood sugar
- Increased liver enzyme levels
- Chills or shivering
- Unusual hair loss or thinning
- Sore, creamy yellow, raised patches in the mouth (thrush)

Peripheral neuropathy

Some cancer treatments can affect the nerves in the body, leading to changes in feeling or sensitivity. This is a condition known as peripheral neuropathy. Your nurse or doctor will monitor you for signs and symptoms of peripheral neuropathy before each of your treatment cycles.

Please refer to the patient information leaflet for brentuximab vedotin for full information on possible side effects, which can be found at <https://www.medicines.org.uk/emc/product/2859/pil>.

What can be done about side effects of brentuximab vedotin?

Your healthcare team can help with side effects, and you should always tell your nurse or doctor about any potential side effects as early as possible.



You might be worried that your treatment will be stopped if you have side effects, but rest assured there are other ways of dealing with them. Your doctor or nurse will develop a plan that could involve adding supportive treatment, reducing the dose, or a temporary break in treatment to help you manage the side effects.

Reporting of side effects



This medicine is subject to additional monitoring. This will allow quick identification of any new safety information. You can help by reporting any side effects you may get.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>. By reporting side effects you can help provide more information on the safety of this medicine.

What happens after my treatment with brentuximab vedotin?

This will depend on your particular circumstances and what you and your care team hope to get out of treatment. Your care team will recommend continuing treatment to completion for as long as they deem appropriate. It's always a joint decision based on how the cancer is responding to brentuximab vedotin and how you're feeling on treatment. Always keep your care team informed of how you are feeling and ask questions if there is something you don't understand.

Communicating with your nurse or doctor is an important aspect in helping you with your treatment. Follow these tips to help get the most from conversations with your healthcare team.



Prepare your questions

Whenever you think of a question, write it down. Remember to look at your questions before your appointment.



Don't hesitate to get in contact

Ask your healthcare team for the best way to get in touch and note down any contact details they give you. If something is bothering you, don't wait for your next scheduled appointment to talk to your doctor or nurse, particularly if you are experiencing new or worsening symptoms or if you are having side effects.



Make sure you understand

Don't be afraid to ask for clarification if you don't understand the answers to your questions.



Work in partnership

The more active you can be in managing your own treatment the more you'll feel in control. Regular contact with your healthcare team will help create the best partnership possible.

Independent patient support organisations

These charities can give you information, practical advice and support about living with lymphoma.

Lymphoma
action 

Inform | Support | Connect

0808 808 5555
www.lymphoma-action.org.uk

Bloodwise

The **blood cancer research** charity

0808 2080 888
www.bloodwise.org.uk

Leukaemia Care

YOUR Blood Cancer Charity

0808 801 0444
www.leukaemiacare.org.uk

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