Adcetris®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Adcetris?

Adcetris contains the active ingredient brentuximab vedotin. Adcetris is used to treat patients with stage III or stage IV Hodgkin Lymphoma who have not had treatment before or to treat Hodgkin Lymphoma that has come back or not responded to previous treatment. Adcetris may be used to lower the likelihood of Hodgkin Lymphoma coming back after a stem cell transplant in patients with certain risk factors. Adcetris is also used to treat patients with cutaneous T-Cell Lymphoma who have previously received at least one anti-cancer medicine that travels through the bloodstream and to treat patients with Peripheral T-Cell Lymphoma who have not had treatment before. Adcetris may also be used to treat Systemic Anaplastic Large Cell Lymphoma that has come back or not responded to previous treatment. For more information, see Section 1. Why am I using Adcetris?.

2. What should I know before I use Adcetris?

Do not use if you have ever had an allergic reaction to brentuximab vedotin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use Adcetris? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Adcetris and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Adcetris?

Adcetris will be given to you by your doctor or nurse, through a drip in one of the veins in your arm (intravenous infusion) over about 30 minutes. More instructions can be found in Section 4. How do I use Adcetris? in the full CMI.

5. What should I know while using Adcetris?

Things you should do	• Read this leaflet carefully before you start using this medicine. It contains important information. • Remind any doctor, dentist or pharmacist you visit that you are using Adcetris. • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not stop using Adcetris without checking with your doctor. • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how Adcetris affects you.

	• If you feel dizzy, do not drive or use tools or machines.
Looking after your medicine	• Keep the unopened vial in a refrigerator stored between 2-8 degrees C. Do not freeze. • Keep the vial in the original carton in order to protect from light.

For more information, see Section 5. What should I know while using Adcetris? in the full CMI.

6. Are there any side effects?

Upper respiratory tract infection, pneumonia, back pain, constipation, nausea, vomiting, feeling tired, frequent urination, increased thirst, change in appetite, weight loss, irritability, unusual bleeding/bruising under skin or bleeding gums, headaches, dizziness, looking pale, itching, hair loss/thinning, muscle pain, joint pain or painful, swollen joints, blisters which may crust/scab, skin redness, pain, swelling, blistering or peeling at infusion site, increased liver enzymes, new or recurring cytomegalovirus infection, sore creamy-yellow raised patches in the mouth, cold sores, trouble sleeping, pain on urination. Serious side effects: confusion or trouble thinking clearly, memory loss, blurred vision, loss of vision, decreased strength/control or sensation in arms or legs, change in way you walk, problems with balance, new or worsening shortness of breath or cough,

decreased urination, heart rhythm disturbances, change sensitivity of skin, numbness, tingling, discomfort, burning sensation or weakness or pain in hands or feet, weakness and difficulty walking, loss of appetite, pain in upper right side of stomach, yellowing of skin or white part of eyes, severe skin problems such as itchiness, redness, rash with swelling, blistering or peeling or rash when exposed to sun, possibly with joint pain and general fever, swelling of face, lips, mouth tongue or throat which may cause difficulty swallowing or breathing, severe upper stomach pain with or without nausea and vomiting or stomach pain that spreads to back.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Adcetris®

Active ingredient(s): *brentuximab vedotin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Adcetris. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Adcetris.**

Where to find information in this leaflet:

1. Why am I using Adcetris

Adcetris contains the active ingredient brentuximab vedotin.

Adcetris belongs to a group of medicines known as anti-cancer agents. There are many different classes of anti-cancer agents.

Adcetris is designed to work differently than traditional anti-cancer agents (chemotherapy). Traditional chemotherapy enters the blood and kills both cancer cells and healthy cells that divide rapidly. Adcetris is made up of a monoclonal antibody linked to a substance intended to kill cancer cells. This substance is delivered to cancer cells by the monoclonal antibody.

A monoclonal antibody is a protein which recognises certain cancer cells.

Hodgkin Lymphoma

Adcetris is used to treat patients with stage III or stage IV Hodgkin Lymphoma who have not had treatment before. When Adcetris is used to treat stage III or stage IV Hodgkin Lymphoma that has not already been treated, it is given in combination with other chemotherapy medicines used to treat this condition.

Adcetris is also used to treat Hodgkin Lymphoma that has come back or not responded to previous treatment.

Adcetris may also be used alone to lower the likelihood of Hodgkin Lymphoma coming back after a stem cell transplant in patients with certain risk factors. In these patients, Adcetris may help prevent or delay recurrence of disease. Your doctor will discuss the potential risks and benefits of receiving Adcetris following a stem cell transplant.

Hodgkin Lymphoma is a type of cancer of the white blood cells.

Cutaneous T-Cell Lymphoma

Adcetris is also used to treat patients with cutaneous T-Cell Lymphoma (CTCL) who have previously received at least one anti-cancer medicine that travels through the bloodstream.

CTCL is a cancer of a certain type of white blood cell called a ‘T-cell’ that mainly affects the skin. Adcetris is used to treat CTCL where a specific type of protein is present on the cells’ surface.

Peripheral T-Cell Lymphoma

Adcetris is also used to treat patients with Peripheral T-Cell Lymphoma (PTCL) who have not had treatment before.

PTCL is a type of non Hodgkin Lymphoma found in the lymph nodes and/or throughout other parts of the body. When Adcetris is used to treat PTCL that has not already been treated, it is given in combination with other chemotherapy medicines used to treat this condition.

Systemic Anaplastic Large Cell Lymphoma (sALCL) is a type of PTCL. Adcetris may also be used alone to treat sALCL that has come back or not responded to previous treatment.

2. What should I know before I use Adcetris?

Warnings

Do not use Adcetris if:

- you are allergic to brentuximab vedotin, or any of the ingredients listed at the end of this leaflet.
- some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- you are currently taking a medicine called bleomycin, an anti-cancer agent.
- always check the ingredients to make sure you can use this medicine.
- the expiry date printed on the pack has passed or if the packaging is damaged or shows signs of tampering. If it has expired or is damaged return it to your pharmacist for disposal.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes.
- have, or think you have, an infection.
- are taking, or have previously taken, medicines which may affect your immune system, such as chemotherapy or immunosuppressive agents. If you are taking or have taken medicines which affect your immune system, you may have an increased risk of infections.
- have or have had any problems with your kidneys or liver.
- have any other medical conditions.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are intending to get pregnant or father a child. You and your partner must use two methods of effective contraception during your treatment with this medicine. Women must continue using contraception for 6 months following the last dose of Adcetris.

Men being treated with Adcetris are advised to have sperm samples frozen and stored before treatment. Men are advised not to father a child during treatment with this medicine and for up to 6 months following the last dose of this medicine.

Tell your doctor if you are pregnant, think you may be pregnant or are breastfeeding. Your doctor can discuss the risks and benefits involved.

Use in Children

Adcetris is to be given to adults only. There is not enough information to recommend the use of this medicine for children under the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Adcetris and affect how it works. These include:

- medicines used in the treatment of fungal infections such as ketoconazole or itraconazole.

These medicines may be affected by Adcetris, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Adcetris.

4. How do I use Adcetris?

How much to use

- Your doctor will decide what dose and how long you will receive Adcetris.
- The dose of Adcetris depends on your body weight. The usual recommended dose of Adcetris when it is given alone is 1.8 mg/kg, given once every 3 weeks. Your doctor may lower your starting dose if you have kidney or liver problems.

- If you are a patient with stage III or stage IV Hodgkin Lymphoma that has not already been treated, you will receive Adcetris in combination with doxorubicin, vinblastine and dacarbazine which are other medicines used to treat this condition.

  See the Consumer Medicine Information leaflets for these medicines given in combination with Adcetris for additional information on their use and effects.

  The usual dose of Adcetris given in combination with doxorubicin, vinblastine and dacarbazine is 1.2 mg/kg given every 2 weeks for 6 months. Your doctor may lower your starting dose if you have mild liver problems.

- If you are a patient with PTCL that has not already been treated, you will receive Adcetris in combination with cyclophosphamide, doxorubicin, and prednisone which are other medicines used to treat this condition.

  See the Consumer Medicine Information leaflets for these medicines given in combination with Adcetris for additional information on their use and effects.

  The usual dose of Adcetris given in combination with cyclophosphamide, doxorubicin, and prednisone is 1.8 mg/kg given every 3 weeks for approximately 4 - 6 months. Your doctor may lower your starting dose if you have mild liver problems.

- After the first dose of Adcetris in combination with chemotherapy, your doctor may also give you a medicine that will help prevent development or reduce

the severity of neutropenia (decrease of white blood cell count) which can increase the risk of infection.

How Adcetris is given

- Adcetris will be given to you by your doctor or nurse, through a drip in one of the veins in your arm (intravenous infusion) over about 30 minutes.
- Your healthcare provider will monitor you during and after the Adcetris infusion for side effects to see if you have a reaction to the treatment.

How long to take it

- Continue receiving your medicine for as long as your doctor tells you.
  You should not stop using Adcetris without talking with your doctor first.

If you forget to use Adcetris

If you forget or miss an appointment to receive the infusion, make another appointment as soon as possible.

If you are not sure what to do, ask your doctor.

If you use too much Adcetris

As Adcetris is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given Adcetris, tell your doctor or nurse immediately.

If you think that you have used too much Adcetris, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Adcetris?

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving Adcetris.
- Tell any other doctors, dentists and pharmacists who treat you that you are receiving this medicine.
- If you are going to have surgery, tell the surgeon that you are receiving this medicine.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do regular blood tests to make sure it is safe for you to receive this medicine and to help prevent unwanted side-effects. Some patients receiving Adcetris may

develop some serious conditions requiring immediate treatment.

Tell your doctor straight away if you notice any of the following symptoms because some of them may be signs of a serious or possibly fatal condition:

Progressive multifocal leukoencephalopathy (PML)

PML is a serious and life-threatening brain condition.

Tell your partner or caregiver you are receiving Adcetris and ask them to tell you if they notice any changes in your movement or behaviour.

Symptoms of PML can include:

- confusion or trouble thinking clearly
- memory loss,
- blurred vision or loss of vision
- decreased strength/control or sensation in your arms or legs, a change in the way you walk or problems with your balance

Lung problems

Tell your doctor straight away if you develop new or worsening shortness of breath or cough.

These could be symptoms of a side-effect called pulmonary toxicity.

Liver injury

Tell your doctor straight away if you develop a loss of appetite, pain in the upper right side of your stomach area, nausea, vomiting, yellowing of your skin or the white part of your eyes (jaundice).

These could be symptoms of a side-effect called hepatotoxicity.

Inflammation of the pancreas

Tell your doctor straight away if you get any of the following symptoms:

- severe upper stomach pain with or without nausea and vomiting or stomach pain that spreads to your back.

These could be symptoms of a condition called pancreatitis.

Infection

Tell your doctor right away if you get any of the following symptoms:

- fever (greater than or equal to 38°C) and/or chills or shivering
- sore throat
- cough
- pain on urination

These could be symptoms of an infection and/or caused by a condition called febrile neutropenia (lack of white blood cells).

Infusion Reactions

Medicines of this type (monoclonal antibodies) can cause infusion reactions. 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. Symptoms of infusion reactions include:

- rash, shortness of breath, difficulty breathing or a tight chest, fever and back pain.

If you think you have previously had a similar reaction, tell your doctor before you are given this medicine.

Severe Skin Reactions

Tell your doctor right away if you experience flu-like symptoms followed by a painful red or purplish rash that spreads and blisters.

These could be symptoms of rare, serious disorders called Stevens-Johnson syndrome, Toxic Epidermal Necrolysis and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Gastrointestinal (bowel) problems

Tell your doctor straight away if you get any of the following symptoms:

- severe stomach pain,
- chills
- nausea, vomiting or diarrhoea

Other serious symptoms

Tell your doctor right away if you get any of the following symptoms:

- hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) which may include fever, extensive skin rash, swollen lymph nodes, blood abnormalities and inflammation of internal organs like the liver, lungs or kidneys
- a potentially-life threatening condition called tumour lysis syndrome in which you may experience dizziness, decreased urination, confusion, vomiting, nausea, swelling, shortness of breath, or heart rhythm disturbances
- a condition called peripheral neuropathy which can change the sensitivity of the skin, causing symptoms such as numbness, tingling, discomfort, a burning sensation, weakness, or pain in the hands or feet
- a condition called motor neuropathy, which can cause symptoms that include a feeling of weakness and difficulty walking

The above list includes very serious side effects. You may need urgent medical attention. Many of these side effects are rare.

Things you should not do

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not stop using Adcetris without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Adcetris affects you. This medicine may have a minor influence on your ability to drive or use tools or machines.

Adcetris may cause dizziness in some people.

If you feel dizzy, do not drive or use tools or machines.

Looking after your medicine

- Keep the unopened vial in a refrigerator stored between 2-8 degrees C. Do not freeze.
- Keep the vial in the original carton in order to protect from light.
- Do not use this medicine after the expiry date.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• upper respiratory tract infection • pneumonia, a type of lung infection • back pain • constipation, nausea, vomiting • feeling tired, frequent urination, increased thirst, changes in your appetite with unintended weight loss, and irritability, these could be symptoms of a condition called hyperglycaemia (high blood sugar)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• unusual bleeding or bruising under the skin or bleeding from your gums, symptoms of a condition called thrombocytopenia caused by low levels of platelets in your blood • headaches, experience dizziness, look pale, may be caused by a condition called anaemia (decreased number of red blood cells) • itching • unusual hair loss or thinning • muscle pain • joint pain or painful, swollen joints • blisters which may crust or scab • skin redness, pain, swelling, blistering or peeling at the infusion site • increased liver enzyme levels (something that	

Less serious side effects	What to do
your doctor will measure for you) • new or recurring cytomegalovirus (CMV) infection • sore, creamy-yellow, raised patches in the mouth (thrush) • cold sores • trouble sleeping • pain on urination	

Serious side effects

Serious side effects	What to do
• confusion or trouble thinking clearly, memory loss, blurred vision or loss of vision, decreased strength/control or sensation in your arms or legs, a change in the way you walk or problems with your balance • new or worsening shortness of breath or cough	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• decreased urination • heart rhythm disturbances • change the sensitivity of the skin, numbness, tingling, discomfort, a burning sensation, weakness, or pain in the hands or feet • a feeling of weakness and difficulty walking • loss of appetite, pain in the upper right side of your stomach area, yellowing of your skin or the white part of your eyes (jaundice) • severe skin problems such as itchiness, redness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints and general fever • swelling of the face, lips, mouth tongue or throat which may cause	

Serious side effects	What to do
difficulty in swallowing or breathing • Inflammation of the pancreas - symptoms may include severe upper stomach pain, with or without nausea and vomiting or stomach pain that spreads to your back.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Adcetris contains

Active ingredient **(main ingredient)**	**Each vial of Adcetris contains 50 mg of brentuximab vedotin.** **After reconstitution each mL of** **solution contains 5 mg of** **brentuximab vedotin.**
Other ingredients **(inactive ingredients)**	trehalose dihydrate sodium citrate dihydrate citric acid monohydrate polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

Adcetris does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

What Adcetris looks like

Adcetris is a white to off-white cake or powder provided in a glass vial.

Each pack of Adcetris consists of one vial (AUST R 203372).

Who distributes Adcetris

Adcetris is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Ph: 1800 012 612

www.takeda.com/en-au

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