Adcetris®

brentuximab vedotin

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Adcetris.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Adcetris is used for

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.

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.

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.

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.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

Before you are given Adcetris

When you must not be given it

Do not receive Adcetris if you have an allergy to:

- **any medicine containing brentuximab vedotin**
- **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.

Do not receive Adcetris if you are currently taking a medicine called bleomycin, an anti-cancer agent.

If you are not sure if you should start receiving Adcetris, talk to your doctor.

Before you are given it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or think you have, an infection.

Tell your doctor if you 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.

Tell your doctor if you have or have had any of the following medical conditions:

- **kidney problems**
- **liver problems**

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.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Adcetris.

The safety of Adcetris beyond 12 months of treatment has not been established.

Use in children

The safety and effectiveness of Adcetris has not been established in children.

Taking other medicines

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

Some medicines and Adcetris may interfere with each other. 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.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while receiving Adcetris.

How Adcetris is given

Adcetris is given by an infusion into a vein (intravenous infusion) over 30 minutes by a healthcare professional. You will be monitored during and after the infusion.

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.

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.

Adcetris is to be given to adults only. It is not for use in children.

Overdose

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 immediately.

While you are receiving Adcetris

Things you must do

If you are of child bearing potential, you and your partner should use two methods of effective contraception during treatment with Adcetris.

If you become pregnant while you are receiving this medicine, tell your doctor or pharmacist immediately.

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:

- stomach pain with or without nausea and vomiting

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 and Toxic Epidermal Necrolysis.

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 side-effects

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Adcetris.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

See the 'While you are receiving Adcetris' section above for a list of serious side effects which you must be

particularly aware of. Tell your doctor immediately if you notice any of the symptoms listed above.

The following is a list of other symptoms and conditions that can occur:

- upper respiratory tract infection
- pneumonia, a type of lung infection
- constipation
- 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)
- 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 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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe skin rash, itching, hives
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing

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

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

After using Adcetris

Storage

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.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it 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.

Ingredients

Adcetris contains 50 mg of brentuximab vedotin as the active ingredient:

It also contains

- citric acid monohydrate
- sodium citrate dihydrate
- trehalose dihydrate
- polysorbate 80.

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

Supplier

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

Adcetris is supplied in New Zealand by:

Takeda New Zealand Limited

Level 10, 21 Queen Street

Auckland 1010

New Zealand

Tel: 0508 169 077

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