TECARTUS®

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 given TECARTUS?

TECARTUS also known as brexucabtagene autoleucel is a type of medicine called a "genetically modified cell therapy". TECARTUS is used to treat mantle cell lymphoma and B-cell precursor acute lymphoblastic leukaemia in adults. Mantle cell lymphoma and B-cell precurosor acute lymphoblastic leukaemia are cancers that affects part of the immune system (the lymph tissue). They affect a type of white blood cell called B lymphocytes. In both mantle cell lymphoma and B-cell precursor acute lymphoblastic leukaemia, B lymphocytes grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood. TECARTUS is used to treat this condition when other available medicines have stopped working for you.

For more information, see Section 1. Why am I given TECARTUS? in the full CMI.

2. What should I know before I use TECARTUS?

Do not use if you have ever had an allergic reaction to brexucabtagene autoleucel 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 am given TECARTUS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TECARTUS 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 am I given TECARTUS?

- TECARTUS is made specially for you as a single administration of your own modified white blood cells.
- Your doctor will give you TECARTUS by a drip (*infusion*) into a vein (*intravenously*).

More instructions can be found in Section 4. How am I given TECARTUS? in the full CMI.

5. What should I know after receiving TECARTUS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have been given TECARTUS. • Plan to stay within proximity (i.e. within 2 hours) of the hospital where you will be treated for at least 4 weeks after you have been given TECARTUS.
Driving or using machines	• Do not drive or operate machinery in the 8 weeks after receiving TECARTUS.

For more information, see Section 5. What should I know after I am given TECARTUS? in the full CMI.

6. Are there any side effects?

There can be some serious side effects before and after TECARTUS treatment. Serious side effects may include symptoms of cytokine release syndrome (CRS), disturbances of brain function or infection.

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.

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

TECARTUS®

Active ingredient(s): *brexucabtagene autoleucel*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TECARTUS. **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 TECARTUS.**

Where to find information in this leaflet:

1. Why am I given TECARTUS?

TECARTUS also known as brexucabtagene autoleucel is a type of medicine called a "genetically modified cell therapy". TECARTUS is made specially for you as a single administration of your own modified white blood cells. It is given by a drip (*infusion*) into a vein (*intravenously*).

TECARTUS is used to treat mantle cell lymphoma (MCL) and B-cell precursor acute lymphoblastic leukaemia (ALL) in adults. Mantle cell lymphoma and B-cell precursor acute lymphoblastic leukaemia are cancers that affects part of the immune system (the lymph tissue). They affect a type of white blood cell called B-lymphocytes. In both mantle cell lymphoma and B-cell precursor acute lymphoblastic leukaemia, B-lymphocytes grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood. TECARTUS is used to treat this condition when other available medicines have stopped working for you.

2. What should I know before I am given TECARTUS?

Warnings and Precautions

Do not use TECARTUS if:

- You are allergic to brexucabtagene autoleucel, or any of the ingredients listed at the end of this leaflet.

Tell your doctor (or your doctor will check) if you:

- have problems with your nervous system (such as fits, stroke, or memory loss).
- have kidney problems.
- have low blood cell levels (blood counts).
- have any problems with your lungs, heart or blood pressure (low or high).
- have had a stem cell transplant in the last 4 months
- have signs or symptoms of graft versus host disease. This happens when transplanted cells attack your body, causing symptoms such as rash, nausea, vomiting, diarrhoea and bloody stools.
- notice the symptoms of your cancer are getting worse. If you have lymphoma this might include fever, feeling weak, night sweats, sudden weight loss
- have an infection. The infection will be treated before the TECARTUS infusion.
- have had hepatitis B, hepatitis C or human immunodeficiency virus (HIV) infection.

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?

Plan to stay within proximity (i.e. within 2 hours) of the hospital where you will be treated for at least 4 weeks after you have been given TECARTUS.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

This is because the effects of TECARTUS in pregnant or breast feeding women are not known, and it may harm your unborn baby or your breast feeding child.

You will be given a pregnancy test before treatment starts. TECARTUS should only be given if the results show you are not pregnant.

If you are pregnant or think you may be pregnant after treatment with TECARTUS, talk to your doctor immediately.

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.

Before you are given TECARTUS tell your doctor or nurse if you are taking any medicines that weaken your immune system such as corticosteroids, since these medicines may interfere with the effect of TECARTUS.

In particular, you must not be given certain vaccines called live vaccines:

- In the 6 weeks before you are given the short course of chemotherapy (called lymphodepleting chemotherapy) to prepare your body for the TECARTUS cells.
- During TECARTUS treatment.
- After treatment while the immune system is recovering.

Talk to your doctor if you need to have any vaccinations.

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

4. How am I given TECARTUS?

Tests and Checks

Before you are given TECARTUS your doctor will:

- Check your lungs, heart and blood pressure.
- Look for signs of infection; any infection will be treated before you are given TECARTUS.
- Check if your cancer is getting worse.
- Look for signs of graft-versus-host disease that can happen after a transplant.
- Check your blood for uric acid and for how many cancer cells there are in your blood. This will show if you are likely to develop a condition called *tumour lysis syndrome*. You may be given medicines to help prevent the condition.
- Check for hepatitis B, hepatitis C or HIV infection.
- Check if you had a vaccination in the previous 6 weeks or are planning to have one in the next few months.

How much you will be given

- Since TECARTUS is made from your own white blood cells, your cells will be collected from you to prepare your medicine.
- Your doctor will take some of your blood using a catheter placed in your vein (a procedure call leukapheresis [loo-kah-fur-ee-sis]).
- Some of your white blood cells are separated from your blood and the rest of your blood is returned to your vein. This can take 3 to 6 hours and may need to be repeated.
- Your white blood cells are sent away to make TECARTUS. It usually takes about 2 to 3 weeks to receive your TECARTUS therapy but the time may vary.
- Prior to receiving TECARTUS, you will be given preparative chemotherapy (called lymphodepleting chemotherapy), which will allow your modified white blood cells in TECARTUS to multiply in your body when the medicine is given to you.
- Your doctor or nurse will check carefully that this medicine is yours.
- In some cases, it might not be possible to go ahead with the planned treatment with TECARTUS. For example: if TECARTUS infusion is delayed for more than 2 weeks after you have received preparatory chemotherapy you may have to receive more preparative chemotherapy.

How you are given TECARTUS

- **TECARTUS will always be given to you by a healthcare professional.**
- **TECARTUS is a single infusion treatment.**
- **During the 30 to 60 minutes before you are given TECARTUS you may be given other medicines. This is to help prevent infusion reactions and fever.**

These other medicines may include:

- **Paracetamol**
- **An antihistamine such as diphenhydramine or similar.**
- Your doctor or nurse will give you a single infusion of TECARTUS into your vein for approximately 30 minutes.
- TECARTUS is the genetically modified version of your normal white blood cells. Your healthcare professional handling TECARTUS will therefore take appropriate precautions (wearing gloves and glasses) to avoid potential transmission of infectious diseases and will follow local biosafety guidelines to clean up or dispose of any material that has been in contact with TECARTUS.
- **You must receive TECARTUS infusion in a qualifed clinical facility and be discharged only when your doctor thinks it is safe for you to go home.**
- You will be monitored where you received your treatment daily for at least 7 days after the infusion.

- Your doctor may do blood tests to check for side effects.

5. What should I know after I am given TECARTUS?

Things you should do

Plan to stay within 2 hours of the hospital where you were treated for at least 4 weeks after you have been given TECARTUS.

If you have MCL, your doctor will recommend that you return to the hospital daily for at least 7 days and will consider whether you need to stay at the hospital as an inpatient for at least 7 days after infusion. This is so your doctor can check if your treatment is working and help you if you have any side effects.

If you have ALL, your doctor will recommend that you return to the hospital daily for at least 10 days and will consider whether you need to stay at the hospital as an inpatient for at least 10 days after infusion. This is so your doctor can check if your treatment is working and help you if you have any side effects.

If you miss any appointments, call your doctor or the qualified clinical facility as soon as possible to reschedule your appointment.

Driving or using machines

Be careful driving or operating machinery.

TECARTUS can cause problems such as altered or decreased consciousness, confusion and seizures (fits) in the 8 weeks following infusion.

Do not drive, use machines, or take part in activities that need you to be alert until at least 8 weeks after your infusion or until your doctor tells you that you have completely recovered.

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.

Very Serious Side Effects

Very Serious Side Effects	What to do
• Symptoms of cytokine release syndrome such as fever, chills, nausea, diarrhoea, headaches, rapid heartbeat, low blood pressure, dizziness, lightheadedness, and trouble breathing • Disturbances of brain function such as loss of consciousness or decreased level of consciousness, confusion or memory loss, difficulty speaking or slurred speech, involuntary shaking of a body part (*tremor*), delirium, agitation, disorientation, hallucination, irritability • Fever, chills, which may be signs of an infection • Decrease of oxygen reaching body tissues • Leakage of fluids from blood vessels into surrounding tissue. This can lead to a weight gain and difficulty in breathing (oedema) • Failure of the kidneys causing your body to hold onto fluid which can be serious or life threatening • Decreased output of urine (due to kidney problems described above) • Fluid around the lungs (pleural effusion) • Swelling, pain, and warmth in your leg, shortness of breath, or chest pain may be a sign of blood clots • Infections caused by fungi • Breathlessness (respiratory failure) • Changes in heart rhythm • Fits (seizures) • Increase of the pressure inside your skull • Alteration of the blood ability to form clots (coagulopathy): symptoms can include excessive or prolonged bleeding or bruising. • Anaphylaxis	**Tell your doctor at the qualified clinical facility immediately or go to the accident and emergency department at the nearest hospital.** **It is important to tell your doctor that you received TECARTUS and to show them your TECARTUS Patient Alert Card.**

Serious Side Effects

Serious Side Effects	What to do
• Decrease in the number of white blood cells, which are important for fighting infections • Decrease in the number of cells that help clot the blood (*thrombocytopenia*) • Low blood pressure, high blood pressure • Decrease in the number of red blood cells (cells that carry oxygen) which may cause you to feel extremely tired with a loss of energy • Extreme tiredness • Changes in rate of the heartbeat • Nausea, constipation, diarrhoea, abdominal pain, vomiting, difficulty swallowing • Muscle pain, joint pain, bone pain, pain in the extremities of the body • Lack of energy or strength, muscular weakness, difficulty moving, muscle spasm • Headache • Abnormal blood test results (high level of uric acid; sugar (glucose) bilirubin or magnesium, low level of sodium, phosphate, potassium or calcium) • Swelling in the limbs • Skin rash or skin problems • Low levels of antibodies called immunoglobulins, which may lead to infections • Changes in blood test result that report on how the liver is working (high levels of liver enzymes) • Dizziness • Nerve pain • Pain • Loss of control of body movements • Dehydration • Abnormal blood test results (low level of albumin) • Changes in vision which makes it difficult to see things (visual impairment) • Hypersensitivity: symptoms such as rash, hives, itching, swelling	**Tell your doctor immediately.**

Less Serious Side Effects	What to do
• Dry mouth • Decreased appetite, sore mouth • Difficulty sleeping, anxiety	**Tell your doctor immediately.**

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 used in a qualified treatment centre.

What TECARTUS contains

Active ingredient (main ingredient)	brexucabtagene autoleucel The active substance is autologous anti-CD19-transduced CD3+ cells. Each patient-specific single infusion bag contains a dispersion of anti-CD19 CAR T cells in approximately 68 mL for a target dose of 2×10^6 anti-CD19 CAR-positive viable T cells/kg for mantle cell lymphoma patients and a target dose of 1×10^6 anti CD19 CAR-positive viable T cells/kg for B-cell precursor acute lymphoblastic leukaemia patients.
Other ingredients (inactive ingredients)	• 5% DMSO • sodium chloride • human serum albumin

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

What TECARTUS looks like

TECARTUS is a clear to opaque, white to red dispersion for infusion, supplied in an infusion bag individually packed in a metal cassette. A single infusion bag contains approximately 68 mL of cell dispersion.

ARTG No: 371431, 396794

Who distributes TECARTUS

Gilead Sciences Pty Ltd

Level 6, 417 St Kilda Road

Melbourne, Victoria 3004

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