CARVYKTI®

Consumer Medicine Information (CMI) summary

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

▼ This gene therapy product is new. Please report side effects. See the full CMI for further details.

1. Why am I receiving CARVYKTI?

CARVYKTI consists of your own white blood cells that have been genetically modified.

CARVYKTI is used to treat patients with cancer of the bone marrow called multiple myeloma. It is given when at least one other treatment has not worked.

CARVYKTI is given to adults aged 18 years and older.

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

2. What should I know before I receive CARVYKTI?

- Do not receive if you have ever had an allergic reaction to any of the ingredients listed at the end of the full 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.

CARVYKTI should not be given to children under 18 years.

For more information, see Section 2. What should I know before I receive CARVYKTI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CARVYKTI and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I receive CARVYKTI?

Your doctor or nurse will give CARVYKTI to you at a qualified treatment centre. You will receive one infusion.

More information can be found in Section 4. How do I receive CARVYKTI? in the full CMI.

5. What should I know after receiving CARVYKTI?

Things you should do	• **Familiarise yourself with the side effects which may require urgent medical attention.** • **Call your doctor straight away if you:** Notice signs of severe allergic reaction or any other side effect requiring urgent medical attention. • Plan to stay near the hospital where you were treated for at least 4 weeks after you have CARVYKTI.
Driving or using machines	• Do not drive or use machines for 8 weeks after CARVYKTI. Some of the side effects of CARVYKTI listed in section 6 may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

For more information, see Section 5. What should I know after receiving CARVYKTI? in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. CARVYKTI can cause side effects that may be serious or life-threatening. Get medical help straight away if you get any of the following serious side effects which may be severe and can be fatal.

- A serious immune reaction called 'cytokine release syndrome (CRS)'
- Effects on your nervous system, symptoms of which can occur days or weeks after you receive the infusion, and may be signs of a serious immune reaction called 'immune effector cell associated neurotoxicity syndrome' (ICANS) or may be signs and symptoms of parkinsonism
- CARVYKTI may increase the risk of life-threatening infections that may lead to death

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.

▼ This therapy is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BOXED WARNING

CYTOKINE RELEASE SYNDROME

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

IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, has occurred following treatment with CARVYKTI, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI. Provide supportive care and/or corticosteroids as needed.

CARVYKTI®

Active ingredient(s): *ciltacabtagene-autoleucel*

Consumer Medicine Information (CMI)

This CMI provides important information about using CARVYKTI. **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 CARVYKTI.**

Where to find information in this CMI:

1. Why am I receiving CARVYKTI?

CARVYKTI contains the active ingredient ciltacabtagene-autoleucel.

CARVYKTI is a therapy used to treat patients with cancer of the bone marrow called multiple myeloma. It is given when at least one other treatment has not worked.

CARVYKTI is given to adults aged 18 years and older.

CARVYKTI is different from other cancer medicines. This is because:

- It is made specially for you from your own white blood cells.
- These cells have been changed (genetically modified) to recognize and attack the cancer cells.

2. What should I know before I receive CARVYKTI?

Warnings

Patients treated with CARVYKTI may develop new types of cancers. There have been reports of patients developing cancer, beginning in a type of white blood cells called T-cells, after treatment with CARVYKTI and similar medicines. Talk to your doctor if you experience any new swelling of your glands (lymph nodes) or changes in your skin such as new rashes or lumps.

Do not receive CARVYKTI if:

- if you are allergic to any of the ingredients of this medicine at the end of this CMI.

Tell your doctor if you have:

- current or past problems with your nervous system - such as fits, stroke, new or worsening memory loss
- any lung, heart or blood pressure (low or raised) problems
- liver or kidney problems
- 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.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given CARVYKTI.

Tests and checks

Before you have CARVYKTI your doctor will:

- check your blood counts
- check your lungs, heart and blood pressure
- look for signs of infection - an infection will be treated before you have CARVYKTI

- check if your cancer is getting worse
- check for hepatitis B, hepatitis C or HIV infection
- check if you had a vaccination in the last 6 weeks or plan to have one in the next few months

After you have CARVYKTI your doctor will:

- regularly check your blood counts, as the number of blood cells and other blood components may decrease.

Tell your doctor right away if you get a fever, chills or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

Look out for serious side effects

CARVYKTI can cause serious side effects that you need to tell your doctor or nurse about straight away and which may require you to get immediate medical attention.

After receiving CARVYKTI 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

Check with your doctor if you are pregnant or intend to become pregnant. You will be given a pregnancy test before treatment starts. CARVYKTI should only be given if the results show you are not pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed. This is because the effects of CARVYKTI in pregnant or breast-feeding women are not known. CARVYKTI may harm your unborn baby or your breast-fed child.

If you have had CARVYKTI treatment, you should discuss any plans to have future pregnancies with your doctor.

Children and adolescents younger than 18 years of age

CARVYKTI should not be used for children aged below 18 years.

No information is available on the use of CARVYKTI in children and adolescents younger than 18 years of age.

3. What if I am taking other medicines?

Before you have CARVYKTI tell your doctor or nurse if you are taking:

- corticosteroids or other medicines that weaken your immune system.

These medicines may interfere with the effect of CARVYKTI.

Vaccines and CARVYKTI

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 CARVYKTI cells
- during CARVYKTI treatment
- after CARVYKTI treatment while your immune system is recovering

Tell your doctor if you have been given another injection or are taking any other medicines or vaccines, including any over-the counter (OTC) medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

4. How do I receive CARVYKTI?

How CARVYKTI is given

CARVYKTI will always be given to you by a healthcare professional at a qualified treatment centre.

Making CARVYKTI from your own blood cells

CARVYKTI is made from your own white blood cells. Your blood cells will be collected from you to prepare your medicine.

- Your doctor will take some of your blood using a catheter (tube) placed in your vein
- Some of your white blood cells are separated from your blood - the rest of your blood is returned to your vein. This process is called 'leukapheresis'
- This process can take 3 to 6 hours and may need to be repeated
- Your white blood cells are sent to the manufacturing centre where they are changed (genetically modified) to make CARVYKTI
- While CARVYKTI is made you may get other medicines to treat the multiple myeloma. This is so it does not get worse

Medicines given before CARVYKTI treatment

A few days before - you will be given treatment called 'lymphodepleting therapy' to prepare your body to receive CARVYKTI. This treatment reduces the number of white blood cells in your blood, so the genetically modified white blood cells in CARVYKTI can grow in numbers when they are returned to your body.

30 to 60 minutes before - you may be given other medicines. These may include:

- medicines called anti-histamines for an allergic reaction - such as diphenydramine
- medicines for fever - such as paracetamol

Your doctor or nurse will check carefully that the CARVYKTI treatment is from your own genetically modified white blood cells.

How you are given CARVYKTI

CARVYKTI is a one-time treatment. It will not be given to you again.

- Your doctor or nurse will give you a single infusion of CARVYKTI into your vein. This is called an 'intravenous infusion' and takes about 30 - 60 minutes.

CARVYKTI is the genetically modified version of your white blood cells.

- Your healthcare professional handling CARVYKTI will take appropriate precautions to prevent the chance of transfer of infectious diseases.
- They will also follow local guidelines to clean up or dispose of any material that has been in contact with CARVYKTI.

5. What should I know after receiving CARVYKTI?

After you have CARVYKTI

- Plan to stay near the hospital where you were treated for at least 4 weeks after you have CARVYKTI.
    - You will need to return to the hospital every day for at least 14 days after you have CARVYKTI. This is so your doctor can check if your treatment is working and treat you if you get any side effects. You may be hospitalised if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.
    - If you miss any appointments, call your doctor or qualified treatment centre as soon as possible to make a new appointment.
- Having CARVYKTI in your blood may cause some commercial HIV tests to incorrectly give you a HIV positive result even though you may be HIV negative.
- Do not donate blood, organs, tissues or cells for transplants after you have had CARVYKTI.

If you have any further questions on the use of this therapy, ask your doctor, pharmacist or nurse.

Driving or using machines

Do not drive, or use tools, or machines until at least 8 weeks after having CARVYKTI, or if symptoms of falling asleep or loss of balance or coordination return.

Looking after your medicine

The following information is intended for doctors only.

Do not use this medicine after the expiry date which is stated on the container label and infusion bag after 'EXP'.

Store frozen in vapour phase of liquid nitrogen (≤-120 °C) until thawed for use. Do not refreeze.

6. Are there any side effects?

Less serious side effects

Less serious side effects	What to do
• Side effects due to infections like infected nose, sinuses or throat, pneumonia (lung infection), urinary tract infection, severe infection throughout body (sepsis), bacterial, fungal and viral infections, fever, feeling very tired, chills, • Side effects affecting the nervous system including nerve damage that may cause tingling, numbness, pain or loss of pain sensation, muscle tremor, weak muscles that cause partial paralysis, facial numbness, difficulty moving muscles of face and eyes, damage to nervous system, difficulty sleeping, severe confusion, headache, altered mental state and confusion, dizziness, problem being able to produce or control movement including muscle spasms, muscle tightness, muscular weakness, muscle and joint pain • Side effects affecting the heart, kidney and circulation like fast heartbeat, abnormal heart rhythm, decreased and increased blood pressure, kidney failure, blood clotting problems, swelling due to fluid build-up, low number of a neutrophils, with a fever, severe bleeding (haemorrhage), serious condition where fluid leaks out of the blood vessels into the body tissues (capillary leak syndrome), serious immune reaction involving the blood cells - may lead to an enlarged liver and spleen, called 'haemophagocytic lymphohistiocytosis', a new type of cancer beginning in a type of white blood cells called T-cells (secondary malignancy of T-cell origin) • Side effects affecting the lungs and airways like cough, short of breath, low blood oxygen • Side effects affecting the gut like diarrhoea, nausea, constipation, vomiting, abdominal pain, decreased appetite, inflamed stomach and gut. • skin rash	**Speak to your doctor immediately if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• A serious immune reaction called 'cytokine release syndrome (CRS)'; some signs include: o chills, fever (38°C or higher, which can also be a sign of infection) o fast heartbeat o difficulty breathing o low blood pressure, which can make you feel dizzy or lightheaded	**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.**
• Effects on your nervous system, symptoms of which can occur days or weeks after you receive the infusion and may initially be subtle. Some of these symptoms may be signs of a serious immune reaction called 'immune effector cell associated neurotoxicity syndrome' (ICANS): o feeling confused o less alert, disorientated, anxious, memory loss o difficulty speaking or slurred speech o slower movements, changes in handwriting o loss of coordination, affecting movement and balance o difficulty reading, writing and understanding words o personality changes which may include being less talkative, disinterest in activities and reduced facial expression o signs and symptoms of parkinsonism:	**Seek immediate medical attention should signs and symptoms of neurologic toxicities occur after recovery from CRS and/or ICANS.**
• CARVYKTI may increase the risk of life-threatening infections • A serious immune reaction called 'Immune Effector Cell-associated Enterocolitis', which can occur weeks or months after you receive the infusion. Some symptoms include: o severe or prolonged diarrhoea and weight loss o gut perforation If you get any of the above side effects get medical help straight away.	

You may experience the following side effects when your doctor orders blood tests:

- o increased levels of enzymes in the blood (alkaline phosphatase, gamma glutamyltransferase and transaminases)
- o increased levels of protein ferritin in the blood
- o increased level of C-reactive protein in blood (may indicate infection or inflammation)
- o high level of bilirubin in blood
- o low levels of albumin, sodium, potassium, calcium, phosphate and magnesium in the blood
- o low number of white blood cell (neutrophils)
- o low numbers of red blood cells (anemia)
- o low numbers of platelets (help blood to clot),
- o low numbers of white blood cells called lymphocytes
- o low levels of antibodies called immunoglobulins may cause infections
- o increased number of a type of white blood cell (lymphocytes)

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.

7. Product details

What CARVYKTI contains

Active ingredient (main ingredient)	ciltacabtagene autoleucel
Other ingredients (inactive ingredients)	• The other ingredients are a solution (Cryostor CS5) used to preserve frozen cells. • CARVYKTI contains dimethylsulfoxide (DSMO) and may contain traces of kanamycin (an "aminoglycoside antibiotic") both of which can sometimes cause allergic reactions

Do not receive this therapy if you are allergic to any of these ingredients.

What CARVYKTI looks like

CARVYKTI is a suspension of your white blood cells, that have been genetically modified, suspended in either a 30 mL or 70 mL patient-specific infusion bag.

AUST R 410143

AUST R 481782

Who distributes CARVYKTI?

JANSSEN-CILAG Pty Ltd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

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