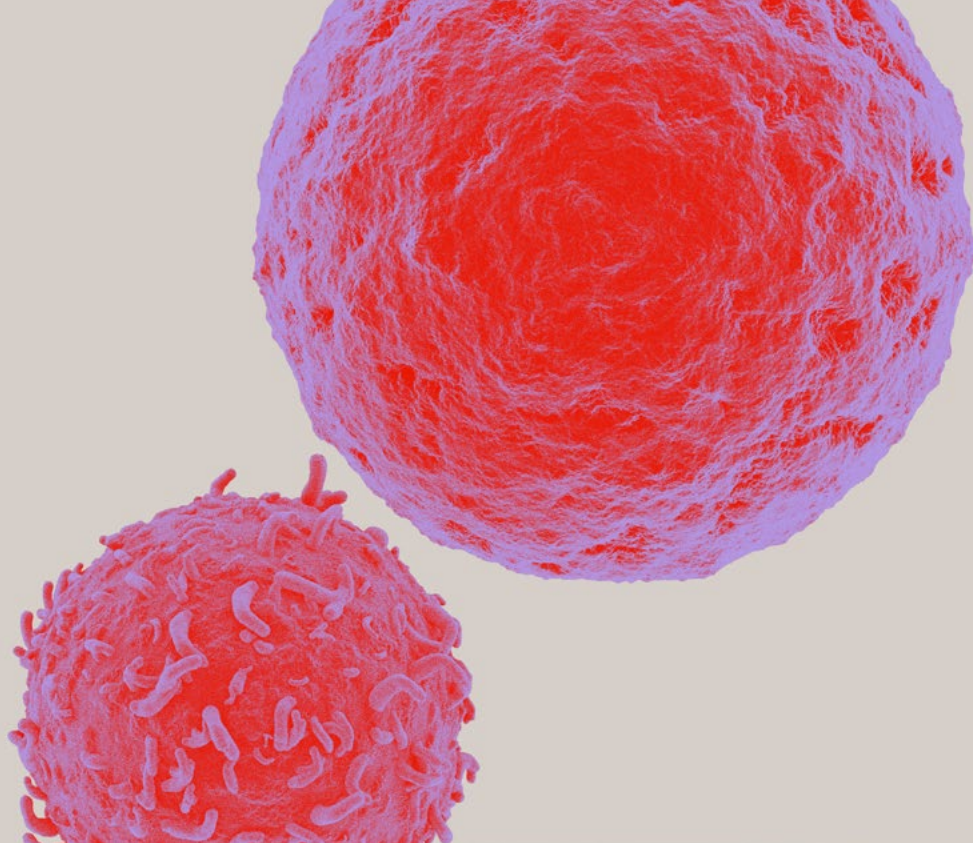




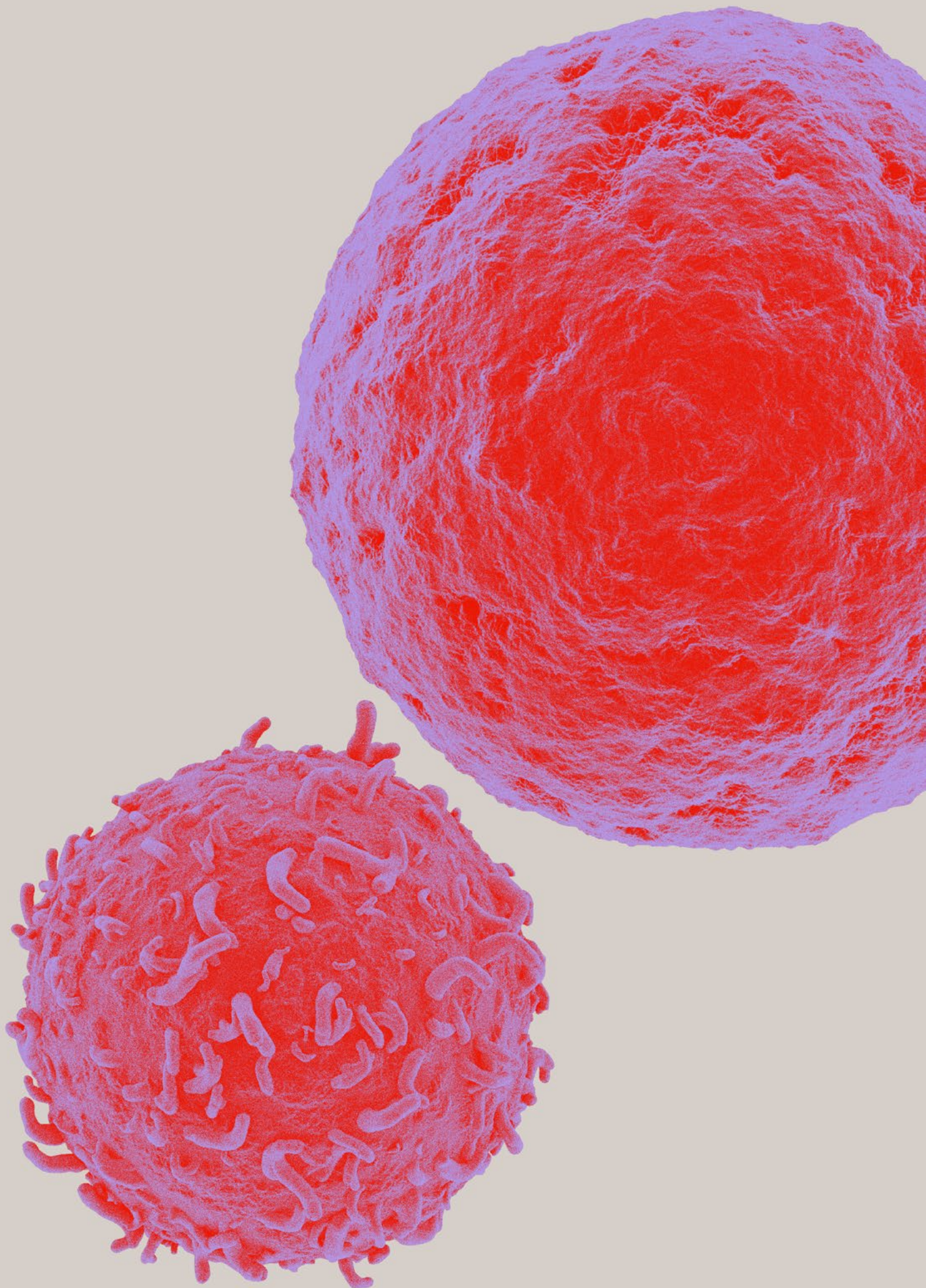
My CAR-T Journey Guide

Ciltacabtagene autoleucel
CARVYKTI[®]▼

Reporting of side effects: ▼ This medicine 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 directly via HPRA Pharmacovigilance. Website: www.hpra.ie. Side effects should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson Company, on +44 1494 567447 or at dsafety@its.jnj.com.

Johnson & Johnson

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Welcome to the start of your CAR-T journey

To help support you through your CAR-T cell therapy, this guide contains information about the treatment, as well as resources to assist you with questions and logistics around the process. This guide is not meant to replace the Patient Information Leaflet, but to provide you with additional information to help improve your understanding of some of the risks involved with CAR-T cell therapy and help you manage these risks better. This guide and the Patient Information Leaflet will help you understand specific topics that you should become familiar with in order to minimise risk. Each section will help you understand more about what to expect at each step and provide you with details about the visits and assessments that you will experience during CAR-T cell therapy and afterward.

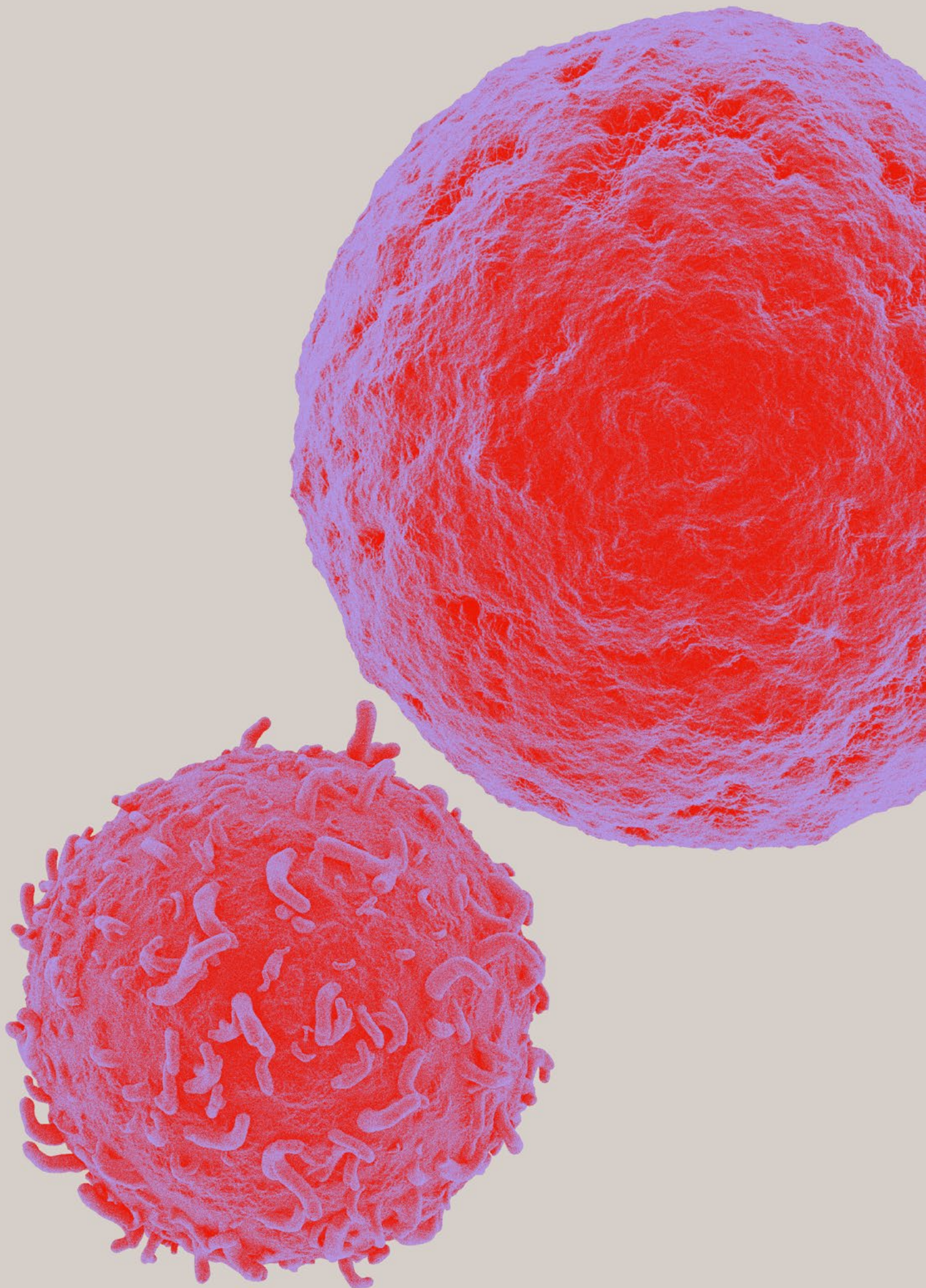
THIS GUIDE BELONGS TO

IF LOST RETURN TO

This guide should not replace the advice and guidance from your healthcare team. If you have additional questions or would like more detailed information please contact your healthcare team.

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CAR-T overview

What is CAR-T cell therapy?

Chimeric antigen receptor (CAR) T cell therapy is a type of immunotherapy that helps your immune system fight cancer. CAR-T cell therapy can be used to fight multiple myeloma and other diseases. T cells—a type of white blood cell—are part of the immune system and are responsible for attacking any bacteria or foreign cells in the body. During CAR-T cell therapy, some of your own T cells will be collected from you. Your T cells will then be reprogrammed at a manufacturing centre to become CAR-T cells. The CAR-T cells are then reintroduced into your system through an infusion. Once the cells are modified and placed back into your body, they can recognise and attack your multiple myeloma cells.¹⁻³

What is ciltacabtagene autoleucel?

Ciltacabtagene autoleucel is a type of CAR-T cell therapy used to treat adult patients with cancer of the bone marrow called multiple myeloma. It is given when at least one other treatment has not worked.⁴ Ciltacabtagene autoleucel may also be referred to as 'cilta-cel', 'CARVYKTI®' or 'your CAR-T cells'.

Please note that some patients may not be eligible for CAR-T cell therapy. Eligibility depends on multiple factors, including the patient's medical history, and will be determined based on patient safety and the likelihood of a positive treatment outcome.⁵

Your eligibility will be assessed by your doctor and specialists from the CAR-T centre. If you are eligible, your doctor will discuss with you whether CAR-T cell therapy is the best therapeutic option.⁵

1. Ali SA, et al. Blood. 2016;128(13):1688–700. 2. Levine BL, et al. Mol Ther Methods Clin Dev. 2016;4:92–101.

3. Janeway CA, et al. In: Immunobiology: The Immune System in Health and Disease, 5th ed; New York: Garland Science; 2001.

4. CARVYKTI 3.2 × 10⁶–1.0 × 10⁸ cells dispersion for infusion Summary of Product Characteristics.

5. Hayden PJ, et al. Ann Oncol. 2022;33(3):259–275.



Safety and monitoring after your CAR-T infusion

After receiving your CAR-T infusion, your healthcare team will monitor you to check if your treatment is working and help you if you have any side effects. Plan to stay near the hospital where you were treated for at least 4 weeks after you are given ciltacabtagene autoleucel.¹

You will need to return to the hospital every day for at least 14 days after you are given ciltacabtagene autoleucel. This is so your doctor can check if your treatment is working and treat you if you get any side effects. If you do develop serious side effects, you may need to stay in the hospital until your side effects are under control and it is safe for you to leave. If you miss any appointments, call your doctor or a qualified treatment centre as soon as possible to make a new appointment.¹

Ask your healthcare team about a detailed plan for how you will be monitored after the infusion.

For your safety, any side effects experienced following infusion of ciltacabtagene autoleucel, even those that seem minor, should be reported immediately. Because ciltacabtagene autoleucel is a one-time treatment, the emergence of side effects will not affect your treatment. Please speak with your healthcare team about potential side effects.

Recognising an emergency

Ciltacabtagene autoleucel can cause serious side effects that you need to tell your doctor or nurse about straight away.¹ If you or your carer recognise any side effect related to CAR-T cell therapy, it is likely an emergency requiring immediate attention. Patients who have received CAR-T cell therapy have experienced side effects ranging from mild to serious. It is important that you are aware of these possible side effects, as you may experience one or more of them when undergoing CAR-T cell therapy.

It is very important for you to let your healthcare team know immediately about any side effects you might experience throughout your therapy. You can use the monitoring charts on pages 18–25 of this guide to record your temperature and any other symptoms in the 4 weeks after your infusion. Symptoms requiring urgent medical care may occur at any time after receiving CAR-T cell therapy, however, they typically occur within 1 month after CAR-T infusion.

1. CARVYKTI 3.2 x 10⁶–1.0 x 10⁸ cells dispersion for infusion Summary of Product Characteristics.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Ciltacabtagene autoleucel can cause side effects that may be serious or life-threatening.¹ Symptoms that appear mild may quickly worsen, and in addition, symptoms may be delayed and may occur weeks after ciltacabtagene autoleucel infusion.

Tell your doctor or nurse immediately if you have any of the following:

Cytokine release syndrome (CRS)¹

Very common (may affect more than 1 in 10 people):

- Chills, fever (38°C or higher, which can also be a sign of infection), fast heart beat, difficulty breathing, low blood pressure which can make you feel dizzy or lightheaded.

These may be signs of a serious immune reaction known as 'cytokine release syndrome' (CRS).

Neurologic toxicities¹

- Neurologic toxicities occur frequently following treatment with ciltacabtagene autoleucel and can be fatal or life-threatening.
- Effects on your nervous system, symptoms of which can occur days or weeks after you receive the infusion, and may initially be subtle:

Very Common (may affect more than 1 in 10 people):

- Feeling confused, less alert, disorientated, anxious or having memory loss*
- Difficulty speaking or slurred speech*
- Slower movements, changes in handwriting*

Common (may affect up to 1 in 10 people):

- Loss of coordination, affecting movement and balance*
- Difficulty reading, writing and understanding words*
- Personality changes, which may include being less talkative, disinterest in activities and reduced facial expression

Some of these symptoms may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS) or may be signs and symptoms of parkinsonism.

Other neurologic toxicities include movement and neurocognitive toxicity with signs and symptoms of parkinsonism, Guillain-Barré syndrome, peripheral neuropathies and cranial nerve palsies.

*Pay close attention to these and ask your carer to do the same.

1. CARVYKTI 3.2 x 10⁶–1.0 x 10⁸ cells dispersion for infusion Summary of Product Characteristics.

Additional side effects

Ciltacabtagene autoleucel may increase the risk of life-threatening infections that may lead to death. Serious immune reactions involving the blood cells may lead to an enlarged liver and spleen, called ‘haemophagocytic lymphohistiocytosis’.

Please refer to the ciltacabtagene autoleucel Patient Information Leaflet for more information on other possible side effects you may experience.

Your doctor will regularly check your blood, as the number of blood cells and other blood components may decrease.¹

Other side effects are listed below. Tell your doctor or nurse if you get any of these side effects.

Very common¹

(may affect more than 1 in 10 people)

- Infected nose, sinuses or throat (a cold)
- Bacterial infection
- Cough, being short of breath
- Pneumonia (lung infection)
- Viral infection
- Headache
- Sleep problems
- Pain, including muscle and joint pain
- Swelling caused by fluid build up in the body
- Feeling very tired
- Nausea (feeling sick), decreased appetite, constipation, vomiting, diarrhoea
- Problems with movement including muscle spasms, muscle tightness
- Nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- Low levels of antibodies called immunoglobulins in the blood – which may lead to infections

Common¹

(may affect up to 1 in 10 people)

- Low number of white blood cells (neutrophils), which can occur with infection and fever
- Gastroenteritis, immune-mediated enterocolitis (inflamed stomach and gut)
- Stomach pain
- Urinary tract infection
- Fungal infection
- Increased number of a type of white blood cell (lymphocytes)
- Severe infection throughout the body (sepsis)
- Kidney failure
- Abnormal heart beat
- Serious immune reaction involving the blood cells – may lead to an enlarged liver and spleen, called ‘haemophagocytic lymphohistiocytosis’

1. CARVYKTI 3.2 x 10⁶–1.0 x 10⁸ cells dispersion for infusion Summary of Product Characteristics.

Very common¹

(may affect more than 1 in 10 people)

- Low level of oxygen in the blood causing shortness of breath, coughing, headache, and confusion
- Increased blood pressure
- Bleeding, which can be severe, called a 'haemorrhage'
- Abnormal blood tests indicating:
 - Low number of white blood cells (including neutrophils and lymphocytes)
 - Low levels of 'platelets' (cells that help blood to clot) and red blood cells
 - Low levels of calcium, sodium, potassium, magnesium, phosphate in the blood
 - Low levels of 'albumin' a type of protein in the blood
 - Blood clotting problems
 - Increased levels of a protein called 'ferritin' in the blood
 - Increased levels of enzymes in the blood called 'gamma-glutamyltransferase' and 'transaminases'

Common¹

(may affect up to 1 in 10 people)

- Serious condition where fluid leaks out of the blood vessels into the body tissues called 'capillary leak syndrome'
- Increased levels of enzymes in the blood called 'alkaline phosphatase'
- Muscle tremor
- Mild muscle weakness caused by nerve damage
- Severe confusion
- Facial numbness, difficulty moving muscles of face and eyes
- High level of 'bilirubin' in the blood
- Blood clot
- Skin rash
- Increased level of a protein called 'C-reactive protein' in the blood that may indicate an infection or inflammation
- A new type of cancer beginning in blood cells and including bone marrow cells

Uncommon¹

(may affect up to 1 in 100 people)

- Tingling, numbness, and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
- A new type of cancer beginning in a type of white blood cells called T cells (secondary malignancy of T-cell origin)

1. CARVYKTI 3.2 x 10⁶–1.0 x 10⁸ cells dispersion for infusion Summary of Product Characteristics.

Driving and using tools or machines¹

Ciltacabtagene autoleucel can severely affect your ability to drive or use tools or machines causing side effects that may make you feel tired, have balance and coordination problems, feel confused, weak or dizzy. Do not drive or use tools or machines until at least 8 weeks after having ciltacabtagene autoleucel and if these symptoms return.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse.¹ Do not try to treat your symptoms with other medicines on your own. This includes any other side effects not listed in this guide. You can also report side effects directly via: HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.¹

Long-term safety monitoring

CAR-T cell therapy is a new type of therapy for multiple myeloma. Therefore, there is a requirement to collect long-term follow-up data on patients treated with CAR-T cell therapy in order to better understand the long-term effects.

Additional considerations

- Having ciltacabtagene autoleucel in your blood may cause some commercial HIV tests to incorrectly give you a HIV positive result even though you may be HIV negative.¹
- Do not donate blood, organs, tissues or cells for transplants after you have had ciltacabtagene autoleucel.¹

Any side effects should be reported to your CAR-T team as soon as possible. You will be asked to enrol in a registry for at least 15 years in order to monitor your health and better understand the long-term effects of ciltacabtagene autoleucel.¹

1. CARVYKTI 3.2 x 10⁶–1.0 x 10⁸ cells dispersion for infusion Summary of Product Characteristics.

Healthcare team information

Healthcare team contact information

It is important to know who is on your healthcare team and how to get in contact with them. Please use the space below to write down their contact information and function/title (e.g. CAR-T Nurse, CAR-T Coordinator, CAR-T Physician)

Contact details of the CAR-T site

**24/7 EMERGENCY PHONE
NUMBER:**

**PRIMARY CAR-T HEALTHCARE
PROFESSIONAL:**

ADDRESS:

NAME:

PHONE NUMBER:

FUNCTION/TITLE:

BEST TIME TO REACH:

EMAIL:

NAME:

PHONE NUMBER:

FUNCTION/TITLE:

BEST TIME TO REACH:

EMAIL:

NAME:

PHONE NUMBER:

FUNCTION/TITLE:

BEST TIME TO REACH:

EMAIL:

CAR-T patient card for ciltacabtagene autoleucel

Please fill in your information and keep this card with you at all times. In the event of an emergency, call the numbers provided below and go to the CAR-T centre or local hospital right away. Show this card to any healthcare professional that sees you if you must go to a hospital outside of your normal treatment visits.

CUT HERE

Patient Card CARVYKTI®[▼] (ciltacabtagene autoleucel)

PATIENT'S NAME:

Emergency Contact

PATIENT CARER'S NAME:

PATIENT CARER'S PHONE NUMBER:

FOLD HERE

Primary CAR-T Healthcare Professional

HEALTHCARE
PROFESSIONAL'S NAME:

HEALTHCARE
PROFESSIONAL'S
PHONE NUMBER:

CAR-T CENTRE ADDRESS:

CAR-T CENTRE
PHONE NUMBER:

FOLD HERE

Important Information for Patients

Carry this card with you at all times. Show it to any doctor who sees you and when you go to the hospital.

Tell any healthcare professional who sees you that you have been treated with ciltacabtagene autoleucel.

Plan to stay near the hospital where you were treated for at least 4 weeks after you have ciltacabtagene autoleucel.

Do not drive or use tools or machines until at least 8 weeks after ciltacabtagene autoleucel infusion.

Refer to the Patient Information Leaflet for more information.

FOLD HERE

If you experience any newly occurring symptoms, especially any of the symptoms listed on this card, please immediately notify your physician, your treating healthcare professional, or any healthcare professional available.

Ciltacabtagene autoleucel can cause serious side effects such as cytokine release syndrome and neurological toxicities. These symptoms can be life-threatening or even fatal and need to be addressed immediately.

Symptoms that appear mild may quickly worsen.

Symptoms may be delayed and may occur weeks after your infusion.

CUT HERE

Call your treating healthcare professional straight away if you have any of these symptoms:

Cytokine release syndrome (CRS)

Fever (38°C or higher)
Chills
Fast heart beat
Difficulty breathing
Feeling dizzy
or lightheaded

Neurologic toxicity (including ICANS)

Feeling confused
Feeling less alert, disorientated,
anxious or having memory loss
Having difficulty speaking or
slurred speech
Slower movements or changes
in handwriting

FOLD HERE

Information for Healthcare Team to Fill In

Please give this card to your CAR-T healthcare team to fill in the information and return to you.

ON (DATE)

this patient received ciltacabtagene autoleucel, which is a chimeric antigen receptor T cell therapy (CAR-T cell therapy) for multiple myeloma.

(BATCH ID)

FOLD HERE

Important Information for Healthcare Professionals

This patient has received an engineered autologous T-cell immunotherapy product that can lead to severe and even fatal CRS and neurologic toxicity. CRS may involve any organ system. Assess the patient for signs and symptoms of CRS and neurologic toxicity.

See Summary of Product Characteristics for full details.

FOLD HERE

Before providing any treatment, call the primary healthcare professional at the number on the front of the card.
This patient should not donate blood, organs, tissues or cells for transplantation.

Reporting of side effects: ▼ This medicine 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 directly via HPRA Pharmacovigilance. Website: www.hpra.ie. Side effects should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson Company, on +44 1494 567447 or at dsafety@its.jnj.com.

EM-189878
Date of approval: March 2026

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Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 1 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.

Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 2 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.

Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 3 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.

Monitoring during the 4 weeks after CAR-T cell infusion

Date of CAR-T cell infusion: _____

Week 4 (date): _____

	Temperature check 1	Temperature check 2	Blood pressure	Symptoms/side effects
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				

Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 1.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 2.	Other changes that you or your carer feel should be captured (pain, fatigue, mood, appetite, etc.): 3.

Glossary

CAR	Chimeric antigen receptor
CRS	Cytokine release syndrome
HIV	Human immunodeficiency virus
ICANS	Immune effector cell-associated neurotoxicity syndrome

