CARVYKTI® (ciltacabtagene autoleucel) is a treatment used for adult patients who have cancer of the bone marrow called multiple myeloma. It is used when at least four other kinds of treatment have not worked or have stopped working. CARVYKTI® is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells.

CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

AFTER YOUR INFUSION OF CARVYKTI®

MONITORING FOR POTENTIAL SIDE EFFECTS WITH THE HELP OF YOUR HEALTHCARE TEAM

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about CARVYKTI®?

CARVYKTI® may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- fever (100.4°F/38°C or higher)
- chills or shaking chills
- fast or irregular heartbeat
- difficulty breathing
- very low blood pressure
- dizziness/lightheadedness
- effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle such as:
  - feeling confused, less alert or disoriented, having difficulty speaking or slurred speech, having difficulty reading, writing and understanding words, memory loss
  - loss of coordination affecting movement and balance, slower movements, changes in handwriting
  - personality changes including a reduced ability to express emotions, being less talkative, disinterest in activities, and reduced facial expression
  - tingling, numbness and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
  - facial numbness, difficulty moving muscles of face and eyes

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

TABLE OF CONTENTS

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

CARVYKTI® AND YOUR IMMUNE SYSTEM

CARVYKTI® (ciltacabtagene autoleucel) is a treatment used for adult patients who have cancer of the bone marrow called multiple myeloma. It is used when at least four other kinds of treatment have not worked or have stopped working. CARVYKTI® is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells.

Because of the way it works, CARVYKTI® can also affect other white blood cells, such as plasma cells.

CARVYKTI® is an individualized treatment that is prescribed and infused at a Certified Treatment Center.

CARVYKTI® treatment is available only at a CARVYKTI® Certified Treatment Center. These are treatment centers where the doctors and nurses are trained to administer CARVYKTI® and to recognize and help manage side effects.

You've been working closely with your treating physician, as well as nurses and other specially trained members of your healthcare team. Their commitment to you and your health continues through treatment and beyond. They'll work with you to plan your ongoing care, including the continued monitoring and management of your side effects with CARVYKTI®.

Be sure to tell your healthcare team if you think you are experiencing any side effects during your treatment journey.

THE CARVYKTI® REMS PROGRAM

What is the CARVYKTI® REMS Program?

A Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program that the US Food and Drug Administration (FDA) requires for certain medicines with serious safety concerns. Drug companies and healthcare professionals must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS program.

Why does CARVYKTI® have a REMS Program?

Due to the risk of serious side effects such as cytokine release syndrome and neurologic toxicities, which can be life-threatening and lead to death, CARVYKTI® (ciltacabtagene autoleucel) may only be administered at healthcare facilities certified in the CARVYKTI® REMS program.

Your doctor has prescribed CARVYKTI® for you because they believe that benefits of treatment with CARVYKTI® are greater than the risks.

Now that you have received your infusion, it's still important to keep and use your CARVYKTI® Patient Wallet Card. Your CARVYKTI® Patient Wallet Card lets any healthcare professional involved in your care know that you have received CARVYKTI®, and includes information needed to contact your CARVYKTI® treating oncologist.

Be sure to carry your completed CARVYKTI® Patient Wallet Card with you at all times. Show the card to any healthcare professional involved in your care or if you go to the emergency room.

For more information about CARVYKTI® REMS or to download a replacement card if needed, visit **CARVYKTIREMS.com**. Let your primary oncologist and your CARVYKTI® healthcare team know about any medications you've taken or any treatments you received.

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE

CARVYKTI® (ciltacabtagene autoleucel) may cause side effects that are severe or life-threatening and can lead to death

Call your healthcare team or get emergency help right away if you experience any of the following:

- Fever (100.4° F or 38° C or higher)
- Chills or shaking chills
- Fast or irregular heartbeat
- Difficulty breathing
- Very low blood pressure
- Dizziness or lightheadedness

It is important that you tell all of your healthcare team that you have received CARVYKTI®. Your healthcare team may give you other medicines to treat your side effects.

Carry your CARVYKTI® Patient Wallet Card with you at all times. Show the card to any healthcare professional involved in your care and if you go to the emergency room.

Call your healthcare team or get emergency help right away if you experience any of these side effects, some of which can occur days or weeks after you receive the infusion and may initially be subtle, such as:

- Feeling confused, less alert, or disoriented
- Difficulty speaking or slurred speech
- Difficulty reading, writing, and understanding words
- Memory loss
- Loss of coordination affecting movement and balance
- Slower movements
- Changes in handwriting
- Personality changes including reduced ability to express emotions, being less talkative, disinterested in activities, and reduced facial expression
- Tingling, numbness, and pain of hands and feet
- Difficulty walking, leg and/or arm weakness
- Difficulty breathing
- Facial numbness, difficulty moving face and eye muscles

These are not the only side effects you should be aware of while on treatment with CARVYKTI®. For more information, please see the Medication Guide for CARVYKTI® or talk to your healthcare team.

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE (more)

Cytokine release syndrome (CRS)

CRS, including fatal or life-threatening reactions, occurred after ciltacabtagene autoleucel infusion.

CARVYKTI® (ciltacabtagene autoleucel) can cause a side effect called **CRS,** which can be severe or fatal. CRS can occur after treatment with some types of immunotherapy, especially CAR-T therapy. CRS occurs when your immune system becomes overly active. This is caused by the treatment and its effect on the immune cells.

This is why it's important to share any changes in how you're feeling with your healthcare team, regardless of how small they may seem. Your healthcare team are experts trained to manage CRS, and they're ready to support you.

CAR-T=chimeric antigen receptor-T cell.

Signs and symptoms of CRS may include:

- Fever
- Difficulty breathing
- Dizziness or lightheadedness
- Nausea
- Headache
- Fast heartbeat
- Low blood pressure
- Fatigue

Cytokine release syndrome is a serious side effect, and needs to be identified and treated quickly.

In the CARTITUDE-1 study, the majority of patients (95%) experienced CRS.

On average, CRS set in 7 days after infusion and lasted for a median of 4 days (range, 1 to 40 days).

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE (more)

Neurologic side effects

Neurologic toxicities can be life-threatening or even fatal conditions where your central nervous system reacts to the infusion.

CARVYKTI® (ciltacabtagene autoleucel) can cause various neurologic side effects, some of which may be severe or fatal. In the CARTITUDE-1 study, 25 people (26%) experienced neurologic toxicity. About half of these cases were serious or severe.

Some of these neurologic toxicity events can be signs of a serious immune reaction associated with CAR-T therapy called immune effector cell-associated neurotoxicity syndrome, or ICANS.

In the CARTITUDE-1 study, 22 people (23%) experienced ICANS.

All of these people previously had CRS. Of these 22 cases, 5 were severe and 2 were fatal. The remainder (17 cases) were mild to moderate. The median time to onset of ICANS was 8 days (range, 1 to 28 days). The median duration of ICANS was 7.5 days (range, 2 to 927 days).

Other forms of neurologic toxicities that are distinct from ICANS may include **parkinsonism, Guillain-Barré syndrome (GBS), immune mediated myelitis, peripheral neuropathy,** and **cranial nerve palsies.** Some people treated with ciltacabtagene autoleucel in clinical studies have experienced these other forms of neurologic toxicities. In a separate, ongoing study of ciltacabtagene autoleucel, one person died after developing GBS. Your healthcare team will monitor for GBS and provide care as needed.

Signs or symptoms associated with neurologic toxicities, some of which may occur days or weeks following the infusion, may include:

- Confusion
- Disorientation
- Loss of consciousness
- Seizures
- Difficulty speaking, reading, or writing
- Tremor
- Slower movements
- Changes in personality
- Depression
- Tingling and numbness of hands and feet
- Leg and arm weakness
- Facial numbness

These are not all the possible side effects of CARVYKTI®. Tell your healthcare team if you experience any side effects.

CAR-T=chimeric antigen receptor-T cell; CRS=cytokine release syndrome.

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE (more)

Monitoring for neurologic toxicity with the ICE test

Your healthcare team may occasionally use something called the ICE test* to see whether you're experiencing the effects of neurologic toxicity. The ICE test consists of several simple questions or directions for you to respond to.

Your healthcare team may use the ICE test to help detect and measure a type of neurologic toxicity called ICANS (see page 7 for more details). If they do detect signs or symptoms of ICANS, they may perform additional tests to see if you need treatment.

ICANS=immune effector cell-associated neurotoxicity syndrome.

*ICE test=immune effector cell-associated encephalopathy test.

ICE test questions

Orientation

Tell your nurse or doctor what month and year it is, and which city and hospital you are in.

Naming

Identify 3 objects that your nurse or doctor points to.

Following commands

Follow simple directions your nurse or doctor gives you (for example, hold up 2 fingers).

Writing

Write down a simple sentence that your nurse or doctor says to you.

Attention

Count backwards from 100 by tens.

SAFETY PROFILE (more)

Hemophagocytic lymphohistiocytosis (HLH)

HLH is a potentially life-threatening complication that can happen.

In HLH, your immune system generates too many immune cells, which causes severe swelling and can cause damage to your body's cells and organs.

- If you experience CRS or neurological toxicity, your healthcare team may assess you for HLH
- If your healthcare team determines that you're experiencing HLH, they'll give you additional medications to treat it

CRS=cytokine release syndrome.

IMPORTANT CAREGIVER TIP

Be observant, keep contact information handy for the healthcare team, and alert them immediately if you notice any side effects.

These are not all the possible side effects of CARVYKTI® (ciltacabtagene autoleucel). **Tell the healthcare team if the person you care for shows any of the symptoms of the side effects listed or you think they may be having a side effect.**

SAFETY PROFILE (more)

Prolonged and/or recurrent cytopenias

The medical term for lower-than-normal numbers of blood cells is cytopenia. Cytopenias (including specific types of cytopenia like thrombocytopenia and neutropenia) have been seen several weeks after CARVYKTI® (ciltacabtagene autoleucel) infusion. Blood counts will be monitored and supportive care may be initiated by your healthcare team as prolonged cytopenia can result in increased risk of infection or bleeding (thrombocytopenia).

In the CARTITUDE-1 study, 29 people (30%) experienced prolonged serious (Grade 3 or 4) neutropenia and 40 people (41%) experienced prolonged serious (Grade 3 or 4) thrombocytopenia that had not resolved by Day 30 following infusion. Neutropenia occurs when you have too few neutrophils, which are a type of white blood cells. Thrombocytopenia occurs when you have too few platelets, which are a type of blood cell that help your blood clot. In 29 people (31%) who recovered from serious (Grade 3 or 4) neutropenia after 1 month, the median time to recovery was 1.8 months (range, 1.0 to 3.7 months). In 32 people (52%) who recovered from serious (Grade 3 or 4) thrombocytopenia after 1 month, the median time to recovery was 1.9 months (range, 1.1 to 8.5 months).

Signs and symptoms associated with cytopenia may include:

- Fatigue
- Weakness
- Shortness of breath
- Poor concentration
- Dizziness or feeling lightheaded
- Cold hands and feet
- Frequent infections
- Fever
- Bleeding and bruising easily
- Difficulty with stopping bleeding
- Internal bleeding

It's important to remember that your healthcare team has specialized training in managing the side effects associated with a CARVYKTI® infusion.

And remember, your caregiver is also an essential part of your team.

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE (more)

Serious infections

Serious infections, including life-threatening or fatal infections including COVID-19, occurred in patients after ciltacabtagene autoleucel infusion.

Hypogammaglobulinemia

Hypogammaglobulinemia, which is a condition where you have a low level of proteins in your blood, may occur in patients receiving ciltacabtagene autoleucel.

Hypersensitivity reactions

Hypersensitivity reactions occurred in 5 people (5%) following ciltacabtagene autoleucel infusion. All reactions were mild with symptoms including flushing, chest discomfort, tachycardia, wheezing, tremor, and burning sensation.

Secondary malignancies

Patients treated with CARVYKTI® (ciltacabtagene autoleucel) may develop secondary malignancies in other parts of their body following treatment.

Vaccines

Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during CARVYKTI® treatment, and until immune system recovery following your treatment with CARVYKTI®. Your healthcare team will let you know when you can receive vaccinations again.

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

SAFETY PROFILE (more)

Common side effects

The most common side effects of CARVYKTI® (ciltacabtagene autoleucel) include:

- Fever (100.4°F/38°C or higher), chills
- Dizziness or lightheadedness
- Headache, muscle or joint pain, feeling very tired
- Altered mental state, confusion
- Infections
- Low levels of antibodies (immunoglobulins) in the blood
- Cough, being short of breath
- Diarrhea, nausea, decreased appetite, constipation
- Fast or irregular heartbeat
- Problems with blood clotting

CARVYKTI® can increase the risk of life-threatening infections including COVID-19 that may lead to death. Tell your healthcare team right away if you develop fever, chills, or any signs or symptoms of an infection.

CARVYKTI® can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]) which may make you feel weak or tired, or increase your risk of severe infection or bleeding that may lead to death. Sometimes your blood cell counts can return to normal and then fall again. After treatment, your healthcare team will test your blood to check for this. Tell your healthcare team right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

Having CARVYKTI® in your blood may cause some commercial Human Immunodeficiency Virus (HIV) tests to incorrectly give you an HIV-positive result even though you may be HIV-negative.

Be sure to tell your healthcare team if you think you are experiencing any side effects during your treatment journey.

These are not all the possible side effects of CARVYKTI®.
Tell your healthcare team if you experience any side effects.

Please click here to read full Important Product Information, including Boxed Warning, and click here to read Medication Guide. Discuss any questions you have with your healthcare team.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

MONITORING FOR SIDE EFFECTS AFTER TREATMENT

After your infusion of CARVYKTI® (ciltacabtagene autoleucel), your healthcare team at the CARVYKTI® Certified Treatment Center will closely monitor you daily for 10 days following infusion for any signs and symptoms of a reaction to treatment.

You should plan to stay close to the location where you received your treatment for at least 4 weeks. Your healthcare team will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

You'll undergo a variety of tests to measure your progress and monitor your health. Some of these may be done at regular follow-ups, and some may be done if you show other signs or symptoms first. It's important that you undergo all the tests that your healthcare team recommend. If you miss an appointment, call your healthcare team as soon as possible to reschedule. Let your healthcare team know if you're not feeling well.
Refrain from driving or hazardous activities for at least 8 weeks following treatment with CARVYKTI®.

Monitoring blood counts

Your healthcare team will continue to monitor your blood counts after the infusion of CARVYKTI®, which can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]).

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

It's essential that you do have your blood tested when requested by your healthcare team. If you miss an appointment, call your healthcare team as soon as possible to reschedule.

You, your caregiver, and your healthcare team will all work together to monitor for longer-term side effects.

It's also important for you to play an active role in your care and lean on your healthcare team for ongoing support.

Talk with your healthcare team about the potential risks of treatment and how they monitor for reactions.

MONITORING FOR SIDE EFFECTS AFTER TREATMENT (more)

Additional long-term monitoring considerations

During the first four weeks after infusion, your healthcare team at the CARVYKTI® Certified Treatment Center will discuss with you when you may return home. At this point, your Certified Treatment Center team will partner with your primary oncology team to provide long-term monitoring for side effects. You may have follow-up appointments with either or both healthcare teams.

Your healthcare team may perform regular medical tests and additional tests as needed to effectively monitor for side effects.

Keep these additional guidelines in mind for your long-term care:

- Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI®. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare team
- Do not donate blood, organs, tissues, or cells for transplantation at any time after your infusion
- Your healthcare team will monitor you life-long for secondary cancers
- The treatment process can be difficult for both you and your caregiver. Talk to your healthcare team about anything that concerns or bothers either of you. They are available to support you both

YOUR HEALTHCARE TEAM WILL SUPPORT YOU IN YOUR TREATMENT

Your caregiver is an important part of your care team. They can provide encouragement and emotional support, as well as help you with regular tasks at home, transport you to and from medical appointments, and help to ensure you have what you need on a daily basis.

Here are some examples of questions you may want to ask your healthcare team at the CARVYKTI® Certified Treatment Center.

"Is there a contact person who my caregiver or I can call with questions or concerns?"

"How long will my side effects last?"

"How will the monitoring of my progress change now?"

"How often do my primary oncologist and my CARVYKTI® (ciltacabtagene autoleucel) healthcare team communicate?"

"How can I help my healthcare team as they monitor my progress?"

"What support services are available to me?"

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

YOUR HEALTHCARE TEAM WILL SUPPORT YOU IN YOUR TREATMENT (more)

Ask for help from family or friends

A friend or family member can be crucial and even mandatory/required in supporting you in parts of the CARVYKTI® (ciltacabtagene autoleucel) treatment process by:

- Monitoring and tracking side effects
- Scheduling appointments
- Organizing important information
- Providing transportation to appointments and keeping you company
- Helping communicate with your healthcare team (for example, providing medical history and insurance information, and asking questions)
- Helping with responsibilities at home
- Managing your schedule and letting visitors know when you do or don't feel up to seeing them
- Providing emotional support and being there to talk

Use your guidebook, *Key Milestones in Your Treatment With CARVYKTI®*, to track how you respond to treatment and how you're feeling.

FOR CAREGIVERS

If you're a caregiver for someone who has received CARVYKTI®, you can do a lot to provide support after treatment. Be an advocate for the person you care for—if they or you have questions about any part of treatment, ask a member of the Certified Treatment Center staff. They expect you to have lots of questions, and they understand that providing answers to your questions is an important part of a successful treatment. Listen closely to the at-home monitoring instructions you receive from the healthcare team and talk to the person you provide care for regularly about how they're feeling.

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

IMPORTANT SAFETY INFORMATION

What is CARVYKTI® (ciltacabtagene autoleucel)?

- CARVYKTI® is a treatment used for adult patients who have cancer of the bone marrow called multiple myeloma. It is used when at least four other kinds of treatment have not worked or have stopped working
- CARVYKTI® is a medicine made from your own white blood cells, which have been changed (genetically modified) to recognize and attack your multiple myeloma cells

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about CARVYKTI®?

CARVYKTI® may cause side effects that are severe or life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- fever (100.4°F/38°C or higher)
- chills or shaking chills
- fast or irregular heartbeat
- difficulty breathing
- very low blood pressure
- dizziness/lightheadedness
- effects on your nervous system, some of which can occur days or weeks after you receive the infusion, and may initially be subtle such as:
  - feeling confused, less alert or disoriented, having difficulty speaking or slurred speech, having difficulty reading, writing and understanding words, memory loss
  - loss of coordination affecting movement and balance, slower movements, changes in handwriting
  - personality changes including a reduced ability to express emotions, being less talkative, disinterest in activities, and reduced facial expression
  - tingling, numbness and pain of hands and feet, difficulty walking, leg and/or arm weakness, and difficulty breathing
  - facial numbness, difficulty moving muscles of face and eyes

It is important that you tell your healthcare providers that you have received CARVYKTI® and to show them your CARVYKTI® Patient Wallet Card. Your healthcare providers may give you other medicines to treat your side effects.

How will I receive CARVYKTI®?

- CARVYKTI® is made from your own white blood cells, so your blood will be collected by a process called “leukapheresis.” The procedure can take 3 to 6 hours and may need to be repeated

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

IMPORTANT SAFETY INFORMATION (more)

- Your white blood cells are sent to a manufacturing center to make CARVYKTI® (ciltacabtagene autoleucel). It takes about 4–5 weeks from the time your cells are received at the manufacturing site and are available to be shipped back to your healthcare provider, but the time may vary
- While CARVYKTI® is being made, you may get other medicines to treat the multiple myeloma. This is so that your multiple myeloma does not get worse

Before you get CARVYKTI®, your healthcare provider will give you chemotherapy for 3 days to prepare your body.

30 to 60 minutes before you are given CARVYKTI®, you may be given other medicines. These may include:

- medicines for an allergic reaction (antihistamines)
- medicines for fever (such as acetaminophen)

When your CARVYKTI® is ready, your healthcare provider will give CARVYKTI® to you through a catheter (tube) placed into your vein (intravenous infusion). Your dose of CARVYKTI® will be given in one infusion bag. The infusion usually takes approximately 30–60 minutes.

After getting CARVYKTI®, you will be monitored at the certified healthcare facility where you received your treatment for at least 10 days after the infusion.

You should plan to stay close to the location where you received your treatment for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur. You may be hospitalized if you develop serious side effects until your side effects are under control and it is safe for you to leave the hospital.

Your healthcare provider will want to do blood tests to follow your progress. It is important that you have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

What should I avoid after receiving CARVYKTI®?

- Do not drive, or operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get CARVYKTI®. This is because the treatment can cause memory and coordination problems, sleepiness, confusion, dizziness, seizures, or other neurologic side effects as discussed by your healthcare provider
- You must not be given certain vaccines called live vaccines for some time before and after CARVYKTI® treatment. Talk to your healthcare provider if you need to have any vaccinations
- Do not donate blood, organs, tissues, or cells for transplantation

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

IMPORTANT SAFETY INFORMATION (more)

What are the possible or reasonably likely side effects of CARVYKTI®?

The most common side effects of CARVYKTI® include:

- fever (100.4°F/38°C or higher), chills
- dizziness or lightheadedness
- headache, muscle or joint pain, feeling very tired
- altered mental state, confusion
- infections
- low levels of antibodies (immunoglobulins) in the blood
- cough, being short of breath
- diarrhea, nausea, decreased appetite, constipation
- fast or irregular heartbeat
- problems with blood clotting

CARVYKTI® can cause a very common side effect called cytokine release syndrome or CRS, which can be severe or fatal. Symptoms of CRS include fever, difficulty breathing, dizziness or lightheadedness, nausea, headache, fast heartbeat, low blood pressure, or fatigue. Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving CARVYKTI®.

CARVYKTI® can increase the risk of life-threatening infections including COVID-19 that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection.

CARVYKTI® can cause various neurologic side effects, some of which may be severe or fatal. Symptoms include but are not limited to confusion, disorientation, loss of consciousness, seizures, difficulty speaking, reading or writing, tremor, slower movements, changes in personality, depression, tingling and numbness of hands and feet, leg and arm weakness, and facial numbness.

CARVYKTI® can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets [cells that help blood to clot]), which may make you feel weak or tired, or increase your risk of severe infection or bleeding that may lead to death. After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, chills, or any signs or symptoms of an infection, are feeling tired, or have bruising or bleeding.

Having CARVYKTI® in your blood may cause some commercial Human immunodeficiency virus (HIV) tests to incorrectly give you an HIV-positive result even though you may be HIV-negative.

These are not all the possible side effects of CARVYKTI®. Call your healthcare provider if you have any side effect.

You may report side effects to FDA at 1-800-FDA-1088.

cp-258861v4

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CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Visit **CARVYKTI.com** to learn more

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(ciltacabtagene autoleucel) Suspension for IV Infusion