



Brexucabtagene autoleucel (Tecartus®)

Pronounce: BREX-ue-KAB-ta-jeen AW-toe-LOO-sel

Classification: CAR-T immunotherapy

About Brexucabtagene autoleucel (Tecartus®)

This medication is a CD19-directed genetically-modified autologous (self-directed) T cell immunotherapy cancer treatment. T cells, a component of your immune system, are removed from your body through an IV line by a process called leukapheresis. In a lab, they add a chimeric antigen receptor (CAR) to your T cells. These T cells are infused back into your body. CAR gives the T cells the ability to identify, attack and kill cancer cells.

How to Take Brexucabtagene autoleucel

Brexucabtagene autoleucel is given through an intravenous (IV) infusion and your dose will be personalized to you. You may be given chemotherapy in the days prior to infusion to prepare your body for treatment with brexucabtagene autoleucel. Before the brexucabtagene autoleucel infusion, you will be given pre-medications including acetaminophen (Tylenol) and an H1 antihistamine such as diphenhydramine (Benadryl). You will need to be closely monitored after receiving this medication and may be restricted to stay within a certain distance of the treatment facility that infused this medication for several weeks after the dose has been given.

Viruses in your body may reactivate after treatment with this medication. It is standard to be tested for hepatitis b, hepatitis c, and HIV prior to receiving brexucabtagene autoleucel. You should ask your care provider prior to receiving any vaccines.

You should not drive or operate heavy machinery for at least 8 weeks after the medication is given. This medication can cause side effects that can affect your ability to do these tasks.

You should not donate blood, tissue, cells, or organs after receiving this medication.

Possible Side Effects

There are a number of things you can do to manage the side effects of brexucabtagene autoleucel. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Cytokine Release Syndrome

After receiving brexucabtagene autoleucel, large numbers of white blood cells are activated and release inflammatory cytokines which can lead to cytokine release syndrome, sometimes severe cases are referred to as cytokine storms. Signs include high fever, lower than normal blood pressure, difficulty breathing, severe nausea and vomiting, severe diarrhea, chills/shaking, severe muscle and joint pain, and bleeding. This serious side effect can happen up until 4 weeks after the infusion. You should call your provider immediately if you have any signs or symptoms of cytokine release syndrome so that appropriate treatment can be given.

Neurologic Toxicities

This medication may cause serious neurologic issues. These side effects are usually seen within the first 8

weeks after infusion and include headache, seizure, personality changes, anxiety, disorientation, confusion, agitation, and tremors. Notify your care provider immediately if you are experiencing any of these changes.

Secondary Cancers

A secondary cancer is one that develops as a result of cancer treatment for another cancer. This is quite rare, but you should be aware of the risk. The type of cancer this medication may cause is called a T-cell cancer. Mature T-cell cancers, including CAR-positive tumors, may happen as soon as weeks following your infusion. Your provider will monitor your labs closely.

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

This medication may cause life-threatening infections, with or without a decrease in white blood cell counts.

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count may drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F/38°C), chills, sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bathe daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

Central Nervous System (CNS) Effects

This medication may affect the central nervous system. Some side effects are encephalopathy (disease or damage to the brain that can alter the way your brain works), aphasia (unable to understand or express speech), tremor (involuntary quivering movement, especially of the hands and legs), drowsiness, feeling nervous, headache, dizziness, and weakness. If you have any of these symptoms during or after the infusion of brexucabtagene autoleucel, tell your care team right away.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the [count is low](#) you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Hypotension (low blood pressure)

Brexucabtagene autoleucel can cause low blood pressure. Tell your care team if you are feeling dizzy, lightheaded, or feel weak. Be careful when going from a sitting to a standing position, as blood pressure can fall quickly with this movement. Your care team will monitor your blood pressure closely during and after the infusion of brexucabtagene autoleucel.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the [red cell count is low](#), you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Fatigue

[Fatigue](#) is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Tachycardia

This medication can cause increased heart rate, also called tachycardia. You may feel like your heart is racing, chest pain, lightheaded, or short of breath. Call your care provider if you are experiencing any of these side effects.

Lung or Breathing Problems

This medication can cause problems with your breathing and lungs, including low blood oxygen levels (pulse ox), new or worsening cough, shortness of breath, and pleural effusion (a buildup of fluid in and around the lungs). Your care team will be monitoring your breathing closely during and after the infusion of the medication. Tell your care team right away if you feel anything different with your breathing.

Muscle or Joint Pain/Aches and Headache

Brexucabtagene autoleucel can cause [joint or muscle aches and pains](#), which can interfere with quality of life. Be sure to talk to your oncology care team if you develop this side effect. Be sure to discuss which pain relievers you can safely take with your oncology team, as these are not without their own side effects.

Peripheral Edema

Peripheral [edema](#) is swelling of the extremities caused by retention of fluid. It can cause swelling of the hands, arms, legs, ankles and feet. The swelling can become uncomfortable. Notify your oncology care team if you are experiencing any new or worsening swelling.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage [nausea and vomiting](#). In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Tell your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (phosphate, calcium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific

electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for [suggestions to relieve the constipation](#).

Diarrhea

Your oncology care team can recommend medications to relieve [diarrhea](#). Also, try eating [low-fiber](#), bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, uncaffeinated fluid a day to prevent dehydration.

Decrease in Appetite

[Nutrition](#) is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products, and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano, or rosemary to add flavor. Bacon, ham, and onion can add flavor to vegetables.

Rash

Some patients may develop a rash, scaly skin, or red itchy bumps. If you notice a rash or feel itching during the infusion of brexucabtagene autoleucel, tell your care team right away. If the rash persists or happens after the infusion, your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to tell your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on [caring for your skin](#).

Insomnia

Insomnia is a change in sleep and can include not being able to sleep or difficulty falling or staying asleep. This medication can cause or worsen pre-existing insomnia. Inform your healthcare provider if you are experiencing changes in your sleep.

Important but Less Common Side Effects

- **Allergic Reactions:** In some cases, patients can have an allergic reaction to this medication. Signs of a reaction can include: shortness of breath or difficulty breathing, chest pain, rash, flushing or itching, or a decrease in blood pressure. If you notice any changes in how you feel during the infusion, let your care team know right away.

- **Hypogammaglobulinemia:** This medication can cause lowered levels of immunoglobulin. Your levels will be monitored and immunoglobulin will be administered as needed. While your levels are low, you are at an increased risk of getting an infection. Be sure to follow the recommendations above to decrease the chance of an infection. You should not receive any vaccines without talking with your oncology team first.
- **Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome:** This is a rare but serious side effect that causes inflammation of the immune system. If you have persistent fevers, fatigue, headache, feel foggy, enlarged lymph nodes, enlarged liver and spleen, bleeding, clotting issues, rash, change in blood pressure or heart rate, liver is not working right, or low blood counts, contact your provider right away.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should consult with your healthcare team before breastfeeding while receiving this medication.

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