

## Afamitresgene autoleucel (Tecelra)

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### About This Treatment

AFAMITRESGENE AUTOLEUCEL (A fam i TRES jeen AW toe LOO sel) treats sarcoma, a cancer that occurs in bone and soft tissues, such as fat, muscle, and blood vessels. It is made using your own T-cells, a type of white blood cell. Your T-cells will be collected via leukapheresis, a procedure that circulates your blood through a machine and removes some of your T-cells. Your collected T-cells are then genetically modified to recognize your cancer cells and attack them. Afamitresgene autoleucel contains your modified T-cells and is given to you through the vein (IV).

### Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Pain in your chest
- Increased heart rate
- Nausea and vomiting (throwing up)
- Tiredness
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Decreased appetite (decreased hunger)
- Swelling of the hands, feet, or any other part of the body
- Fever
- Infections
- Cytokine release syndrome (CRS): Some types of cancer treatments can cause CRS because of the effects of the treatment in your body. If this happens, you may feel very sick and get a fever, headache, nausea, or feel weak. You may also have changes to your blood pressure. Because of this, your blood pressure and pulse may be checked while you are getting this treatment.
- Back pain
- Trouble breathing
- Low blood pressure

**Note:** Each of the side effects above was reported in 20% or greater of people treated with afamitresgene autoleucel. All possible side effects are not included. Your side effects may be different

*depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.*

## Warnings and Precautions

- Cytokine release syndrome (CRS), which can be life-threatening
- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have hallucinations (see or hear things that are not there), have trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, seizures or coma. **If you start to have any of these symptoms let your care team know right away.**
- Severe bone marrow suppression that may last for several weeks.
- Allergic reactions, including anaphylaxis, are rare but may happen in some people. Signs of allergic reaction may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, you should get urgent medical treatment.**
- Risk of severe and life-threatening infections and neutropenic fever. This is a type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.
- Reactivation of viruses that you may have been exposed to in the past.
- This treatment may raise your risk of getting a another cancer.

**Note:** *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.*

## Important Information

- Because of the possible effect on your central nervous system, this treatment may impair your ability to drive or use machinery. Do not drive or use machinery during your treatment and for at least 4 weeks after treatment.
- This treatment and other medicines may be present in the urine, stool, and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- Do not donate blood, organs, tissues, or cells for transplantation.
- This treatment may cause a false-positive HIV test result.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.



- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicine that can lessen or stop diarrhea, constipation or nausea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- Cytokine release syndrome may happen after your infusion. **If this happens, call 911 for emergency care.**

## Food and Medicine Interactions

- There are no known interactions of afamitresgene autoleucel with food.
- Tell your care team about all the medicines and dietary supplements (vitamins, minerals, herbs and others) that you are taking at this time. The safety and use of dietary supplements and alternative diets are often not known. Using these might affect your cancer or interfere with your treatment. Until more is known, you should not use dietary supplements or alternative diets without your cancer care team's help.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Blurry vision or changes in your eyesight
- Tiredness that interferes with your daily activities



- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Extreme tiredness, agitation, or confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Hallucinations
- Trouble understanding or speaking
- Loss of control of bowels or bladder
- Numbness or lack of strength to your arms, legs, face, or body
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Pain in your chest
- Wheezing and/or trouble breathing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain in your abdomen that does not go away
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Swelling of the hands, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of cytokine release syndrome such as: fever, chills, or shaking chills, feeling dizzy or lightheaded, have a headache and/or have nausea or throwing up. **If this happens, call 911 for emergency care.**
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, trouble urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Pain that does not go away, or is not relieved by prescribed medicines

## Reproduction Warnings

- **Pregnancy warning:** Talk with your care team if you are pregnant or planning to become pregnant while taking this medicine. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- You should also refer to the prescribing information of the chemotherapy medicines you will be receiving in preparation for this treatment and after this treatment.
- **Breastfeeding warning:** Talk with your care team about breastfeeding during treatment. You may need to stop breastfeeding. You should also refer to the prescribing information of the chemotherapy medicines you will be receiving in preparation for this treatment and after this treatment.



- **Fertility warning:** The effect of this medicine on fertility is not known. If you plan to have children, talk with your care team. You should also refer to the prescribing information of the chemotherapy medicines you will be receiving in preparation for this treatment and after this treatment.

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