

Lifileucel (Amtagvi)

About This Treatment

Lifileucel is used to treat cancer. This treatment uses special cells from your own body that can find and destroy cancer cells. A small piece of your tumor will be taken from your body, where the special cells called tumor infiltrating lymphocytes (TILs) will be collected from your tumor and grown in a lab. Once enough cells have been grown, they will be used to create a treatment specifically designed to target and attack your cancer cells. Lifileucel contains your own TILs and is given to you through the vein (IV).

Possible Side Effects

- Increased heart rate
- Diarrhea (loose bowel movements)
- Tiredness
- Fever and chills
- Neutropenic fever. A type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.
- Swelling of the hands, feet, or any other part of the body
- Infection
- Decreased level of oxygen
- Trouble breathing
- Rash
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.
- Low blood pressure

Note: Each of the side effects above was reported in 20% or greater of patients treated with lifileucel. 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 medical team.

Warnings and Precautions

- Changes in your heart function such as abnormal heartbeats, abnormal electrocardiogram (EKG/ ECG) and/or changes in your heart muscles which can affect your heart's ability to pump blood properly. You may be at risk of heart attacks, which can be life-threatening.

- Risk of severe and life-threatening infections
- Abnormal bleeding in your abdomen and/or in your brain, which can be life-threatening.
- 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.
- Changes in your kidney function, which can cause kidney failure and be life-threatening.
- Changes in your lung function such as decreased level of oxygen in your blood, which can be life-threatening.
- Allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of an 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.**
- While you are getting this medicine in your vein (IV), you may have a reaction to the medicine. Sometimes you may be given medicine to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. These reactions may happen after your infusion. If this happens, call 911 for emergency care.

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

Important Information

- Talk to your doctor before receiving any vaccinations during your treatment. Some vaccinations are not recommended while receiving lifileucel.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.

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 doctor or nurse 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 nurse before using dental floss.
- Use an electric shaver instead of a razor.
- Be very careful when using knives or tools.
- Drink enough fluids to keep your urine pale yellow.



- If you 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). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your doctor or nurse about medicines that are available to help stop or lessen diarrhea.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.
- Infusion reactions may occur after your infusion. If this happens, call 911 for emergency care.

Food and Medicine Interactions

- There are no known interactions of lifileucel with food.
- This treatment may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Headache that does not go away
- Blurry vision or changes in your eyesight
- Confusion
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Numbness or lack of strength to your arms, legs, face, or body
- Trouble understanding or speaking
- 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.**
- Feeling that your heart is beating in a fast or not normal way (palpitations)



- Wheezing and/or trouble breathing
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back, or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Severe pain in your abdomen that does not go away
- Swollen abdomen
- Swelling of the hands, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- Decreased or very dark urine
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- 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 infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. If this happens, call 911 for emergency care.
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** It is not known if this treatment may harm an unborn baby. For this reason, be sure to talk with your doctor if you are pregnant or planning to become pregnant while receiving this treatment. Let your doctor know right away if you think you may 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:** It is not known if this treatment passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment because this treatment may enter the breast milk and cause harm to a breastfeeding baby. 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:** Fertility studies have not been done with this treatment. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking. 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.

New February 2024

