



Lifileucel (Amtagvi™)

Pronounce: LIF-i-LOO-sel

Classification: Tumor Derived Autologous T-Cell Immunotherapy

About Lifileucel (Amtagvi™)

Lifileucel (Amtagvi™) is a tumor derived autologous t-cell immunotherapy. T-cells, a part of your immune system, are removed from a part of your tumor in a lab. These T-cells are put back into cancer cells. These T-cells are then infused back into your body after you receive chemotherapy to help your immune system fight the cancer cells.

How to Take Lifileucel (Amtagvi™)

Lifileucel is given through an intravenous (IV) infusion. Your dose will be personalized to you. You will be given chemotherapy in the days before the infusion to prepare your body for treatment with lifileucel. Before the infusion, you will be given pre-medications including acetaminophen (Tylenol) and an H1 antihistamine such as diphenhydramine (Benadryl) to prevent a reaction. Some people do have reactions like fevers, chills, shaking, higher than normal heart rate, rash, low blood pressure, shortness of breath, cough, chest tightness, or wheezing. If you have any changes in how you are feeling, tell your provider right away.

You will be given certain medications hours after your infusion to help your body and immune system recover from the treatment. Corticosteroids should only be taken as prescribed as they can interfere with this treatment.

You will be in the hospital until you have recovered from any serious side effects you are having. Depending on where you received your treatment and how you are doing, you may be asked to stay within 2 hours of the treatment center for several weeks. Your providers will monitor your recovery closely.

Possible Side Effects

There are a number of things you can do to manage the side effects of lifileucel. 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:

Low Blood Counts

The chemotherapy given before this medication may lower your blood counts. This can lead to infection, fever, bleeding, and shortness of breath, along with other side effects. Your blood counts will be closely monitored, and you will be given medications to help your blood counts return to normal. The sections below detail information about low white blood cell, platelet, and red blood cell counts.

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

This medication may cause life-threatening infections. [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.

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. This medication can also cause bleeding inside your body so if you notice new or worsening pain, a swollen belly, nausea or vomiting, your skin becomes pale, clammy, or sweaty, you lose your breath, or you faint, it is important that you contact your provider right away. This could be an emergency. 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.

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.

Heart Issues

This medication can cause heart issues like faster than normal heart rate, atrial fibrillation, arrhythmia, acute myocardial infarction (heart attack), cardiac ventricular thrombosis, cardiomyopathy, and QT prolongation. Your provider will monitor your heart function before, during, and after you receive this medication. If you have any chest pain, shortness of breath, feel like your heart skips a beat, or you faint, you should contact your provider right away, call 911, or go right to the emergency room.

Kidney Issues

This medication can change the way your kidneys work. Your provider will monitor your kidney function and if you have changes in how often or how much you urinate, have new pain with urination, or the color of your urine changes, you should talk to your provider.

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.

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.

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, un-caffeinated fluid a day to prevent dehydration.

Edema

This medication can cause swelling. Contact your provider if you have any new or worsening swelling.

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.

Loss or Thinning of Scalp and Body Hair (Alopecia)

Your hair may become [thin, brittle, or may fall out](#). This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

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. After receiving this medication, you should talk to your provider about when it is safe to try to get pregnant or father a child. You should not breastfeed while taking this medication.

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