

Tisagenlecleucel (Kymriah®)

About This Drug

Tisagenlecleucel is used to treat cancer. It is made using your own T-cells, a type of white blood cell. Your T-cells will be collected via leukopheresis, 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 then grown. Tisagenlecleucel contains your modified T-cells and is given to you through the vein (IV).

Possible Side Effects

- Increased heart rate
- Diarrhea (loose bowel movements)
- Nausea and vomiting (throwing up)
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds or any other unusual bleeding.
- Tiredness
- Swelling
- Fever
- Infections, including viral, bacterial and fungal
- Decreased appetite (decreased hunger)
- Cytokine release syndrome (CRS): Some types of cancer drugs can cause CRS because of the effects of the drug 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. Tell your doctor or nurse right away if you have any of these symptoms while you are getting this drug: fever, chills, or shaking chills, feeling dizzy or lightheaded, have a headache and/or have nausea or throwing up.
- Decreased immunoglobulins in your body, which are antibodies and help you fight off infection
- Headache
- Confusion
- 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, 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 doctor know right away.
- Changes in your kidney function
- Cough
- Decreased level of oxygen

- Low blood pressure

Note: Each of the side effects above was reported in 20% or greater of patients treated with tisagenlecleucel. Not all possible side effects are included above.

Warnings and Precautions

- Cytokine release syndrome (CRS), which can be life-threatening
- Severe changes in your central nervous system, which can be life-threatening
- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug 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, do not take another dose of this drug. You should get urgent medical treatment.
- Bone marrow suppression which could last for a long time. 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 (fatigue), and raise your risk of bleeding.
- Severe infections, including viral, bacterial and fungal, which can be life-threatening
- Low levels of a protein in the body that helps to fight infections (hypogammaglobulinemia).
- This drug may raise your risk of getting a second cancer.

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

- This drug may impair your ability to drive or use machinery. Do not drive or use machinery during your treatment and for 8 weeks after treatment.
- Talk to your doctor before receiving any vaccinations during your treatment. Some vaccinations are not recommended for 2 weeks prior to treatment, while receiving tisagenlecleucel and after receiving tisagenlecleucel - until your immune system is fully recovered.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- Do not donate blood, organs, tissues and cells for transplantation.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities
- If you are dizzy, get up slowly after sitting or lying down.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

- 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.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- 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 doctor's approval, may increase your appetite.
- 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 nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- 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.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation and/or diarrhea.

Food and Drug Interactions

- There are no known interactions of tisagenlecleucel with food
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) you are taking before starting this medicine as there are known drug interactions with tisagenlecleucel. 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
- Easy bleeding or bruising
- Feeling dizzy or lightheaded

- Confusion and/or agitation
- Seizures. Symptoms of a seizure include 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
- Blurry vision or changes in your eyesight
- Numbness or lack of strength to your arms, legs, face, or body
- Headache that does not go away
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Coughing up yellow, green, or bloody mucus.
- Wheezing or trouble breathing
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- 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
- Decreased urine, or very dark urine
- Blood in your urine, vomit (bright red or coffee-ground) and/or stools (bright red, or black/tarry)
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of your legs, ankles and/or feet
- 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 you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug may have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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