PATIENT & CAREGIVER EDUCATION

Tisagenlecleucel

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Kymriah

Brand Names: Canada

Kymriah

Warning

- A severe health problem called cytokine release syndrome (CRS) has happened with this drug. Sometimes, this has been life-threatening or deadly. Get medical help right away if you have signs like chills; confusion; dizziness; fast or abnormal heartbeat; chest pain; change in how much urine is passed; feeling tired or weak; fever; headache; passing out; rash; swelling; trouble breathing; severe muscle or joint pain; yellow skin or eyes; dark urine; severe upset stomach, throwing up, or diarrhea; or wheezing.
- If you have an infection or any inflammatory health problem, talk with your doctor. This drug may not be right for you.
- Nervous system problems have happened after treatment with this drug. Sometimes, these have been severe and life-threatening or deadly. Call your doctor right away if you feel agitated, confused, nervous, sluggish, or restless. Call your doctor right away if you have anxiety, change in balance, change in eyesight, dizziness or passing out, hallucinations (seeing or hearing things that are not there), headaches, seizures, shakiness, trouble speaking, trouble reading or writing, or new or worse behavior or mood changes.
- You will be watched closely for signs of CRS and nervous system problems for at least 7 days after getting this drug. You will also need to stay close to a healthcare facility for at least 2 weeks after getting it.
- This drug may raise the risk of other cancers. This includes certain types of blood cancer. The doctor will watch for this. If you have questions, talk with the doctor.

What is this drug used for?

- It is used to treat types of leukemia and lymphoma.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert for at least 2 weeks after getting this drug. If you have any questions, call your doctor or pharmacist.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Low blood cell counts have happened with this drug. This may last for several weeks after taking this drug. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. Some severe infections have been deadly. If you have questions, talk with the doctor.
- Wash hands often. Stay away from people with infections, colds, or flu.

- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- If you have had hepatitis B before or carry the virus, talk with your doctor. Drugs like this one can cause the virus to become active. This can lead to very bad and sometimes deadly liver problems.
- Hepatitis and HIV testing will be done before taking this drug.
- Talk with your doctor before getting any vaccines. Some types of vaccines must not be given for at least 6 weeks before starting this drug, during treatment, and for some time after your last dose.
- Do not donate blood, organs, tissues, or cells. Talk with your doctor to see when you can do these things after getting this drug.
- If you have upset stomach, throwing up, diarrhea, or decreased appetite, talk with your doctor. There may be ways to lower these side effects.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, you must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If you get pregnant, call your doctor right away.
- If you want to get pregnant after stopping this drug, talk with your doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or

swelling of the mouth, face, lips, tongue, or throat.

- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of high or low blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of electrolyte problems like mood changes; confusion; muscle pain, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.
- Signs of a severe health problem called tumor lysis syndrome (TLS) like fast or abnormal heartbeat; passing out; trouble passing urine; muscle weakness or cramps; upset stomach, throwing up, diarrhea, or not able to eat; or feeling sluggish.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Fast breathing.
- Fast or abnormal heartbeat.
- Trouble sleeping.
- Feeling very sleepy.
- Not able to focus.
- Memory problems or loss.

- Swelling.
- Trouble moving around.
- Bad dreams.
- A burning, numbness, or tingling feeling that is not normal.
- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.
- An immune system problem called hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) has happened with this drug. Sometimes, this has been life-threatening and even deadly. Call your doctor right away if you feel confused or not alert or have fever, swollen gland, rash, seizures, change in balance, or trouble walking that is new or worse.
- A severe brain problem called progressive multifocal leukoencephalopathy (PML) has happened with this drug. It may cause disability or can be deadly. Tell your doctor right away if you have signs like confusion, memory problems, depression, change in the way you act, change in strength on 1 side is greater than the other, trouble speaking or thinking, change in balance, or change in eyesight.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.
- Headache.
- Feeling tired or weak.
- Pain in arms or legs.
- Back, bone, joint, muscle, or neck pain.

- Stuffy nose.
- Weight loss.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- It is given as an infusion into a vein over a period of time.
- Other drugs may be given before this drug to help avoid side effects.

What do I do if I miss a dose?

- Call your doctor to find out what to do.

How do I store and/or throw out this drug?

- This drug will be given in a hospital or doctor's office. You will not store it at home.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour

down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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