Medication Guide

TECELRA® (pronounced tuh-sel-ruh)
(afamitresgene autoleucel)

Read this Medication Guide before you start your TECELRA treatment. Talk with your healthcare provider if you have questions about your health condition or treatment. Reading this Medication Guide does not take the place of talking with your healthcare provider about your treatment.

What is the most important information I should know about TECELRA?

You will likely be in a hospital before and after getting TECELRA.

TECELRA may cause side effects that can be severe or life-threatening. Call your healthcare provider or get emergency help right away if you get any of the following:

Fever (100.4°F/38°C or higher)
Chills/Shivering
Difficulty breathing
Fast or irregular heartbeat
Low blood pressure
Fatigue
Severe nausea, vomiting, or diarrhea
Severe headache
New skin rash

Tell all your healthcare providers that you were treated with TECELRA.

What is TECELRA?

TECELRA is a medicine, called a *genetically modified autologous T cell immunotherapy*, that is used to treat synovial sarcoma. It is used when other kinds of treatment do not work.

TECELRA is different from other cancer medicines because it is made from your own white blood cells that are made to recognize and attack your cancer cells.

Your healthcare provider will perform tests to see if TECELRA is right for you.

Before you get TECELRA, tell your healthcare provider about all your medical problems, including:

Seizure, stroke, confusion, or memory loss

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Heart, liver or kidney problems
Low blood pressure
Lung or breathing problems
Recent or active infection
Past infections which can be reactivated following treatment with TECELRA
Low blood counts
Pregnancy, you think you may be pregnant, or plan to become pregnant
Breastfeeding
Taking a blood thinner

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I get TECELRA?

Since TECELRA is made from your own white blood cells, your blood will be collected by a process called "leukapheresis" (loo-kah-fur-ee-sis). This gets sent to a company to make the TECELRA for you.

It takes about 6 weeks to get your TECELRA back, but the time may vary.

While your TECELRA is being made, your healthcare provider may give you other medicines to stabilize your cancer.

Before you get your TECELRA, you will get 4 days of chemotherapy to prepare your body.

When your TECELRA is ready, you get a tube (intravenous catheter) placed into your vein and your dose of TECELRA will be given in one or more infusion bags. The infusion may take up to 60 minutes for each infusion bag.

After getting TECELRA, you will be monitored daily at the healthcare facility, for at least 7 days after the infusion.

You should plan to stay close to a healthcare facility for at least 4 weeks. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur.

Your healthcare provider will do blood tests to follow your progress. It is important that you have your blood tested. If you miss a scheduled appointment for your collection of blood, call your healthcare provider as soon as possible to reschedule.

What are the possible or reasonably likely side effects of TECELRA?

The most common side effects of TECELRA include:

Nausea
Vomiting
Fatigue
Constipation
Fever (100.4°F/38°C or higher)
Infection
Abdominal pain
Difficulty breathing
Decreased appetite
Diarrhea
Low blood pressure
Back pain
Fast heart rate
Chest pain
General body swelling
Low white blood cells
Low red blood cells
Low platelets

What should I avoid after receiving TECELRA?

Do not drive, operate heavy machinery, or do other activities that could be dangerous for at least 4 weeks after you get TECELRA.

Do not donate blood, organs, tissues, or cells for transplantation.

What are the ingredients in TECELRA?

Active ingredient: afamitresgene autoleucel

Inactive ingredients: Dimethyl Sulfoxide (DMSO)

Issued: Aug 2024