

**MEDICATION GUIDE**  
**ABECMA® (uh-BEK-muh)**  
**(idecabtagene vicleucel)**

Read this Medication Guide before you start your ABECMA treatment. The more you know about your treatment, the more active you can be in your care. 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 ABECMA?**

ABECMA may cause side effects that are life-threatening and can lead to death. Call your healthcare provider or get emergency help right away if you get any of the following:

- difficulty breathing
- fever (100.4°F/38°C or higher)
- chills/shivering
- confusion
- dizziness or lightheadedness
- shaking or twitching (tremor)
- fast or irregular heartbeat
- severe fatigue
- severe nausea, vomiting, diarrhea

It is important that you tell your healthcare providers that you have received ABECMA and to show them your ABECMA Patient Wallet Card. Your healthcare provider may give you other medicines to treat your side effects.

**What is ABECMA?**

ABECMA is for the treatment of multiple myeloma in patients who have received at least two kinds of treatment regimens that have not worked or have stopped working. ABECMA is a medicine made from your own white blood cells; the cells are genetically modified to recognize and attack your multiple myeloma cells.

**How will I receive ABECMA?**

ABECMA is made from your own white blood cells, so your blood will be collected by a process called “leukapheresis” (LOO-kuh-feh-REE-sis).

Your blood cells will be sent to a manufacturing center to make your ABECMA. Based on clinical trial experience, it takes about 4 weeks from the time your cells are received at the manufacturing site and are available to be shipped back to your healthcare provider, but the time may vary.

Before you get ABECMA, your healthcare provider will give you chemotherapy for 3 days to prepare your body.

When your ABECMA is ready, your healthcare provider will give ABECMA to you through a catheter (tube) placed into your vein (intravenous infusion). Your dose of ABECMA may be given in one or more infusion bags. The infusion usually takes up to 30 minutes for each infusion bag.

You will be monitored at the certified healthcare facility where you received your treatment daily for at least 7 days after the infusion.

You should plan to stay within 2 hours of this location for at least 4 weeks after getting ABECMA. Your healthcare provider will check to see that your treatment is working and help you with any side effects that may occur.

### **What should I avoid after receiving ABECMA?**

- Do not drive, operate heavy machinery, or do other activities that could be dangerous if you are not mentally alert, for at least 8 weeks after you get ABECMA. This is because the treatment can cause temporary memory and coordination problems, sleepiness, confusion, dizziness, and seizures.
- Do not donate blood, organs, tissues, or cells for transplantation.

### **What are the possible or reasonably likely side effects of ABECMA?**

The most common side effects of ABECMA are:

- fatigue
- fever (100.4°F/38°C or higher)
- chills/shivering
- severe nausea or diarrhea
- decreased appetite
- headache
- dizziness/lightheadedness
- confusion
- difficulty speaking or slurred speech
- cough
- difficulty breathing
- fast or irregular heartbeat

In a study comparing ABECMA to standard regimen, a higher proportion of patients experienced death within the first 9 months from randomization in the ABECMA arm compared to the standard regimens arm. This higher rate of early death was mainly observed before receiving ABECMA with the main reason being progression of multiple myeloma. There was also an increase in the rate of death from adverse events after ABECMA.

ABECMA can cause a very common side effect called cytokine release syndrome or CRS, which can be severe or fatal. Symptoms of CRS include fever, difficulty breathing, dizziness or light-headedness, nausea, headache, fast heartbeat, low blood pressure, or fatigue. Tell your healthcare provider right away if you develop fever or any of these other symptoms after receiving ABECMA.

ABECMA can increase the risk of life-threatening infections that may lead to death. Tell your healthcare provider right away if you develop fever, chills, or any signs or symptoms of an infection.

ABECMA can lower one or more types of your blood cells (red blood cells, white blood cells, or platelets), which may make you feel weak or tired or increase your risk of severe infection or bleeding. After treatment, your healthcare provider will test your blood to check for this. Tell your healthcare provider right away if you get a fever, are feeling tired, or have bruising or bleeding.

ABECMA may increase your risk of getting cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.

Having ABECMA in your blood may cause a false-positive human immunodeficiency virus (HIV) test result by some commercial tests.

These are not all the possible side effects of ABECMA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **General information about the safe and effective use of ABECMA**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about ABECMA, talk with your healthcare provider. You can ask your healthcare provider for information about ABECMA that is written for health professionals.

For more information, go to ABECMA.com or call 1-888-805-4555.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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