PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ABECMA™

***(idecabtagene vicleucel*)**

Read this carefully before you start taking Abecma and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Abecma.

Serious Warnings and Precautions

Abecma can cause serious side effects. Sometimes, these serious side effects are life-threatening and can lead to death. The following serious side effects have been seen in people taking Abecma:

- Fever and chills which may be symptoms of a serious side effect called cytokine release syndrome (CRS), which can be severe or fatal. Other symptoms of CRS are difficulty breathing, dizziness or light-headedness, nausea, headache, fast heartbeat, low blood pressure or fatigue, vomiting, diarrhea, muscle pain and joint pain.
- Neurological problems like confusion, difficulty with memory, difficulty speaking or slowed speech, difficulty understanding speech, loss of balance or coordination, disorientation, being less alert (decreased consciousness) or excessive sleepiness, loss of consciousness, delirious, fits (seizures), shaking or weakness with loss of movement on one side of the body.
- Fever, low blood pressure, shortness of breath, low blood counts, bleeding, kidney, liver, spleen and other organ damage which may be symptoms of a serious side effect called Hemophagocytic Lymphohistiocytosis/ Macrophage activation syndrome (HLH/MAS) and can be life-threatening or fatal if not recognized early and treated.

Abecma will only be given by an experienced healthcare professional at qualified treatment centres.

What is ABECMA used for?

- Abecma is used to treat adults with a type of cancer called multiple myeloma which is a cancer of the bone marrow.
- It is given when your cancer has not responded to at least three different treatments or has come back after these treatments.

For the following indication Abecma has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional."

- the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and who are refractory to their last therapy.

What is a Notice of Compliance with Conditions (NOC/c)?
A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.
Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does Abecma work?

Abecma is made from your own white blood cells. These cells are taken from your blood and are modified to recognize the myeloma cells in your body. 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 professional. You may be given other therapies to treat your cancer while Abecma is being made. When these cells are introduced back into your blood, they can recognise and attack the myeloma cells.

What are the ingredients in Abecma?

Medicinal ingredients: idecabtagene vicleucel

Non-medicinal ingredients: CryoStor® CS10, Magnesium chloride, Potassium chloride, Sodium acetate trihydrate, Sodium chloride, Sodium gluconate, Water for injection.

Abecma comes in the following dosage forms:

Abecma is a liquid, colourless cell suspension for infusion in one or more infusion bags. Abecma is given to you by drip into a vein as a single, one-time treatment.

Do not use Abecma if:

- you are allergic to Abecma or any of the other ingredients of this medicine (listed in "What are the ingredients in Abecma"?). If you think you may be allergic, ask your doctor for advice.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Abecma. Talk about any health conditions or problems you may have, including if you:

- have any lung or heart problems.
- have low blood pressure.
- have an infection. The infection will be treated before Abecma infusion.
- notice the symptoms of your cancer getting worse. In myeloma this might include fever, feeling weak, bone pain, unexplained weight loss.
- have had a cytomegalovirus, hepatitis B virus, hepatitis C virus or human immunodeficiency virus infection.
- have had a vaccination in the previous 6 weeks or are planning to have one in the next few months.

- have had any symptoms of severe allergic reactions, such as shortness of breath or trouble breathing, skin rash, swelling of the lips, tongue, or face, chest pain, feeling dizzy or faint.
- are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine. This is because the effects of Abecma in pregnant or breast-feeding women are not known and it may harm your unborn baby or breastfed child.
- are pregnant or think you may be pregnant after treatment with Abecma, talk to your doctor immediately. You will be given a pregnancy test before treatment starts. Abecma should only be given if the results show you are not pregnant.
- are a man and you plan to father a child after Abecma treatment.
- are breast-feeding or plan to do so.

Other warnings you should know about:

- Do not drive, operate heavy machinery, or do other activities that could be dangerous 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 and cells for transplantation after Abecma treatment.
- Abecma contains up to752 mg sodium per dose which is equivalent to 37.6 % of the recommended maximum daily intake of sodium for an adult.
- Abecma contains up to 274 mg potassium per dose. This should be taken into consideration if you have reduced kidney function

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Abecma:

- Corticosteroids, chemotherapy, and other medications that can weaken your immune system. This is because these medicines may interfere with the effect of Abecma and may make Abecma less effective.
- Live vaccines: You must not be given certain vaccines called live vaccines:
  - in the 6 weeks before you are given a short course of chemotherapy (called lymphodepleting chemotherapy) to prepare your body for Abecma.
  - during Abecma treatment.
  - after treatment while the immune system is recovering.

Talk to your doctor if you need to have any vaccinations.

How you will receive Abecma:

Giving blood to make Abecma from your white blood cells

- Your doctor will take some of your blood using a tube (catheter) in your vein. Some of your white blood cells will be separated from your blood and the rest of your blood is returned to your body. This is called ‘leukapheresis’ and can take 3 to 6 hours. This process may need to be repeated.
- Your white blood cells will then be frozen and sent away to make Abecma.

Other medicines you will be given before Abecma

- A few days before you receive Abecma, you will be given a short course of chemotherapy. This is to clear away your existing white blood cells.
- Shortly before you receive Abecma, you will be given acetaminophen and an

antihistamine medicine. This is to reduce the risk of infusion reactions and fever.

How Abecma is given to you

- Your doctor will check that the Abecma was prepared from your own blood by checking the patient identity information on the medicine labels matches your details.
- Abecma is given as an infusion drip through a tube into your vein.

After Abecma is given to you

- Stay close to the treatment centre where you received Abecma - for at least 4 weeks.
- You may be monitored daily in the treatment centre for at least 7 days.
- This is so your doctor can check if your treatment is working - and help you if you have any side effects.
- Your doctor will give you a Patient Alert Card. Read it carefully and follow the instructions on it.
- Always show the Patient Alert Card to the doctor or nurse when you see them or if you go to the hospital.
- Your healthcare professional will want to do blood tests to follow your progress. It is important that you do have your blood tested. If you miss an appointment, call your healthcare professional as soon as possible to reschedule.

Usual dose:

Abecma comes as a cell suspension in one or more infusion bag(s). The target dose is 450×10^6 CAR-positive T cells within a range of 275 to 520×10^6 CAR-positive T cells. Abecma should be given to you as a single-dose, one-time treatment.

What are possible side effects from using Abecma?

These are not all the possible side effects you may have when taking Abecma. If you experience any side effects not listed here, tell your healthcare professional.

Very common:

- headache
- feeling dizzy, tired or lack of energy
- fast heartbeat
- low blood pressure, dizziness upon standing or high blood pressure
- cough
- decreased appetite
- constipation
- nausea, vomiting
- diarrhea
- swollen ankles, arms, legs and face
- joint pain
- low number of white blood cells (neutrophils, leucocytes and lymphocytes), with or without fever, which can increase your risk of infection
- laboratory test results showing low levels of antibodies, called immunoglobulins (hypogammaglobulinemia) that are important in fighting infections
- laboratory test results showing increased levels of liver enzymes (abnormal liver function test) or a higher level of a protein (C-reactive protein) in blood that may indicate inflammation.

Common:

- difficulty sleeping
- muscle pain

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Fever, chills, difficulty breathing, dizziness or light-headedness, nausea, headache, fast heartbeat, low blood pressure or fatigue may be symptoms of a side effect called cytokine release syndrome or CRS, which can be severe or fatal.		√	√
Confusion, difficulty with memory, difficulty speaking or slowed speech, difficulty understanding speech, loss of balance or coordination, disorientation, being less alert (decreased consciousness) or excessive sleepiness, loss of consciousness, delirious, fits (seizures), shaking or weakness with loss of movement on one side of the body		√	√
Any signs of an infection, which may include fever, chills or shivering, rapid pulse or depending on the location of infection, you may also experience sore throat, cough, shortness of breath or rapid breathing, chest pain, or painful urine or blood in urine		√	√
Feeling very tired or weak or shortness of breath –which may be signs of low levels of red blood cells (anaemia)		√	√
Bleeding or bruising more easily without cause, including nosebleeds or bleeding from the mouth or bowels, which may be a sign of low levels of platelet cells in your blood		√	√
Shortness of breath with or without exercise		√	

Fatigue, muscle weakness or cramps or an irregular heartbeat which may be a sign of low levels in the blood of calcium, potassium, sodium, magnesium, phosphate or albumin		√	
COMMON			
Severe inflammation due to activation of your immune system which could lead to fever, decrease in blood cell levels, difficulty breathing, low blood pressure, dizziness, an increased risk of bleeding, serious damage to the kidneys, liver, spleen or other organs in the body and could be life-threatening or fatal		√	√
Spontaneous or prolonged and excessive bleeding (coagulopathy)		√	√
Extreme shortness of breath or difficulty breathing, feeling suffocated, anxious, restless, cough, frothy sputum with or without blood, blue colored lips, or fast heartbeat, caused by fluid in the lungs (possible symptoms of pulmonary edema)		√	√
Abnormal body movements or lack of coordination		√	
Uneven or irregular heartbeat		√	
Shortness of breath, confusion or drowsiness which may be a sign of low oxygen level in the blood (hypoxia)		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

If you want more information about Abecma:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.celgene.ca/en, or by calling 1-866-463-6267.

This leaflet was prepared by Celgene Inc., a Bristol Myers Squibb company.

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