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## Abecma 300X10exp6 To 460X10exp6 Cell Intravenous Suspension Antineoplastic – CAR-T Immunotherapy

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### Description

Side Effects Nausea, constipation, headache, tiredness, trouble sleeping, or loss of appetite may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. People using this medication may have serious side effects. However, you have been prescribed this drug because your doctor has judged that the benefit to you is greater than the risk of side effects. Careful monitoring by your doctor may decrease your risk. Tell your doctor right away if you have any serious side effects, including: fast/irregular heartbeat, muscle/joint pain, swelling. Although idecabtagene vicleucel is used to treat cancer, it may rarely increase your risk of developing other cancers. Tell your doctor right away if you develop swollen glands or unusual growths/lumps. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses Idecabtagene vicleucel is used to treat a certain type of cancer (multiple myeloma) that has not gotten better or that has come back after other kinds of treatment. This type of treatment is known as gene therapy. Idecabtagene vicleucel is made from your own white blood cells and is given only to you. The white blood cells have been changed to have a specific protein (chimeric antigen receptor-CAR) that helps your body slow or stop the growth of certain cancer cells. How to use Abecma 300X10exp6 To 460X10exp6 Cell Intravenous Suspension Antineoplastic – CAR-T Immunotherapy Read the Medication Guide provided by your health care professional before you start using this product. If you have any questions, ask your health care professionals. Your doctor will give you 3 days of chemotherapy before treatment with this product to prepare your body. This product is given by slow injection into a vein as directed by your doctor. You will receive one or more injections, one right after another. Each injection is given over about 30 minutes. To decrease the risk of side effects, your doctor may also give you other medications (such as acetaminophen, diphenhydramine) before injecting idecabtagene vicleucel. Your doctor will check you daily for at least 7 days after your treatment to see how well it works and help you manage any side effects. You should plan to stay for at least 4 weeks near the place of your treatment (for example, within 2 hours' drive). Warnings This medication may cause serious (even fatal)

reactions (cytokine release syndrome-CRS, hemophagocytic lymphohistiocytosis-HLH/macrophage activation syndrome-MAS). Careful monitoring and prompt treatment may decrease your risk. Before treatment with this medication, tell your doctor your medical history, especially of any current/recent infection. Tell your doctor right away if you have any symptoms such as high fever, trouble breathing, chills/shaking chills, severe nausea/vomiting/diarrhea, severe muscle/joint pain, very low blood pressure, dizziness/lightheadedness, or signs of kidney problems (such as change in the amount of urine). Serious nerve problems can occur after treatment with idecabtagene vicleucel. Tell your doctor right away if you have drowsiness, seizure(s), mental/mood changes (such as confusion, anxiety, memory loss), or trouble with reading, writing, speaking, or understanding. This product may cause a severe decrease in your blood cells, which lowers your ability to fight infections and increases the risk of anemia/bleeding problems. You may be more likely to get a serious (rarely fatal) infection and any infection you have may get worse. Tell your doctor right away if you have signs of infection (such as a sore throat that doesn't go away, fever, chills, cough), easy or unusual bruising/bleeding, or unusual tiredness. For patients to receive this medication, all doctors, pharmacists, and patients must agree to, understand, and carefully follow the requirements of the Abecma REMS Program. These requirements apply in the United States. If you live in Canada or any other country, consult your doctor and pharmacist for your country's regulations. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. This medication may interfere with certain lab tests (such as some HIV tests), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug. Precautions Before receiving idecabtagene vicleucel, tell your doctor or pharmacist if you have any allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart problems, kidney/liver problems, lung or breathing problems, nerve problems (such as memory loss, seizures), past/current/recent infection. This product can make you more likely to get infections or may make current infections worse. Stay away from anyone who has an infection that may easily spread (such as chickenpox, COVID-19, measles, flu). Talk to your doctor if you have been exposed to an infection or for more details. Tell your health care professional that you are using idecabtagene vicleucel before having any immunizations/vaccinations. Avoid contact with people who have recently received live vaccines (such as flu vaccine inhaled through the nose). To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports. This drug may make you drowsy or dizzy, affect your coordination, or make it harder for you to think clearly. Alcohol or marijuana (cannabis) can worsen these effects. Do not drive, use machinery, or do anything that needs alertness until you can do it safely (at least 8 weeks after receiving treatment is recommended by the manufacturer). Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while using this product. Idecabtagene vicleucel may harm an unborn baby. Your doctor should order a pregnancy test before you start this product. If you become pregnant, talk to your doctor right away about the risks and benefits of this product. It is unknown if this product passes into breast milk. Consult your doctor before breast-feeding.

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## Side Effects

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## Uses

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**Interactions**

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**Other Details**

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