Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Abecma®

Dispersion for intravenous infusion containing 260 - 500 x 10^6 cells

Active ingredient
idecabtagene vicleucel
The dispersion contains 260 - 500 x 10^6 autologous T cells genetically modified to express an anti-BCMA chimeric antigen receptor (CAR-positive viable T cells).

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

In addition to this leaflet, Abecma also has a **patient safety information card**. This card contains important safety information that you need to know before starting and during treatment with Abecma and which you should follow. Carefully read the patient safety information card and patient information leaflet before using this medicine. Keep the card in case you need to read it again.

1. What is this medicine intended for?

Abecma is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Therapeutic group: Other antineoplastic medicines.

Abecma is a type of medicine called a "genetically modified cell therapy". The active ingredient in the medicine is idecabtagene vicleucel, which is made from autologous white blood cells (your own cells), called T cells.

How Abecma works
The white blood cells are taken from your blood and are genetically modified so that they can target the myeloma cells in your body.
When Abecma is infused into your blood, the modified white blood cells will kill the myeloma cells.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6). If you think you may be allergic, ask your doctor for advice.
- If you are allergic to any of the ingredients in the medicines you will be given for lymphodepleting chemotherapy, which is used to prepare your body for Abecma treatment.

Special warnings about using this medicine

Before treatment with Abecma, tell your doctor if:
- you have any lung or heart problems.
- you have low blood pressure.
- you have had a stem cell transplant in the last 4 months.
- you have signs or symptoms of graft-versus-host disease. This happens when the transplanted cells attack your body, causing symptoms such as rash, nausea, vomiting, diarrhoea and bloody stools.
- you have an infection or active inflammatory process (including pneumonitis, myocarditis or hepatitis). The infection will be treated before you are given Abecma.
- you have central nervous system problems or impaired renal or hepatic function.
- you notice the symptoms of your cancer getting worse. In myeloma, these symptoms might include fever, feeling weak, bone pain, unexplained weight loss.
- you have had cytomegalovirus (CMV) infection, hepatitis B or C or human immunodeficiency virus (HIV) infection.
- you have had a vaccination in the previous 6 weeks or are planning to have one in the next few months.

If you think that any of the above cases apply to you (or you are not sure), talk to your doctor before you receive Abecma.

Patients treated with Abecma may develop new types of cancers. There have been reports of patients developing cancer, beginning in a type of white blood cells called T cells, after treatment with Abecma and similar medicines. Talk to your doctor if you feel any new swelling of your glands (lymph nodes) or changes in your skin such as new rashes or lumps.

Children and adolescents
Abecma should not be given to children and adolescents below 18 years of age. There is no information about the safety and efficacy of this medicine in children and adolescents.

Tests and follow-up
Before you receive Abecma, your doctor will:
- Check your lungs, heart and blood pressure.
- Look for signs of infection; any infection will be treated before you receive Abecma.
- Check if your cancer is getting worse.
- Check if you have CMV infection, hepatitis B, hepatitis C or HIV infection.

After receiving Abecma
- There are serious side effects which you need to tell your doctor or nurse about straight away and which may require you to get immediate medical attention. See section 4 under 'Serious side effects'.
- Your doctor will regularly check your blood counts, as the number of blood cells may decrease.
- Stay close to the medical centre where you received Abecma for at least 4 weeks. See sections 3 and 4.
- Do not donate blood, organs, tissues or cells for transplantation.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Medicines that affect your immune system
Before you receive Abecma, tell your doctor or nurse if you are taking any medicines that weaken your immune system such as corticosteroids. This is because these medicines may interfere with the effect of Abecma.

See section 3 for information about the medicines you will be given before receiving Abecma.

Vaccinations
You must not receive 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.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, 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 breast-fed child.
- If you are pregnant or think you may be pregnant after treatment with Abecma, talk to your doctor immediately.
- You must have a pregnancy test before treatment starts. Treatment with Abecma will only be given if the results show you are not pregnant.

Discuss pregnancy with your doctor if you have received Abecma.

Driving and using machines
Do not drive, use machines or take part in activities that need you to be alert for at least 8 weeks after treatment or until your doctor tells you that you have completely recovered. Abecma may make you feel sleepy, may cause confusion or fits.

Important information about some of this medicine's ingredients
Abecma contains sodium, potassium and dimethyl sulfoxide (DMSO)
This medicine contains up to 752 mg sodium (main component of cooking/ table salt) per dose. This is equivalent to 37.6% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains up to 274 mg potassium per dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

If you have not been previously exposed to DMSO, you should be observed closely during the first minutes of the administration of the infusion.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Collecting blood to make Abecma from your white blood cells
- Your doctor will take blood from you using a tube (catheter) inserted into 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. The process 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 to make Abecma.

Other medicines you will receive 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 paracetamol and an antihistamine medicine. This is to reduce the risk of infusion reactions and fever.

How Abecma is given
- Your doctor will check that the Abecma was prepared from your own blood by checking that 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
- Stay close to the medical centre where you received Abecma for at least 4 weeks.
- You may be monitored daily at the medical centre for at least 10 days to check if your treatment is working and help you if you have any side effects. See sections 2 and 4.
- Do not donate blood, organs, tissues or cells for transplantation.

If you miss an appointment
Call your doctor or the medical centre as soon as possible to make another appointment.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Abecma may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects
Tell your doctor immediately if you get any of the following side effects after being given Abecma. They usually happen in the first 8 weeks after the infusion, but can also develop later:

Very common side effects - affect more than one in ten users:
- fever, chills, difficulty breathing, dizziness or light-headedness, nausea, headache, fast heartbeat, low blood pressure or fatigue - these may be symptoms of cytokine release syndrome or CRS, a serious and potentially fatal condition.
- any signs of an infection, which may include fever, chills or shivering, cough, shortness of breath, rapid breathing and rapid pulse.
- feeling extremely tired or weak or short 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 platelets in your blood.

Common side effects - affect 1-10 in 100 users:
- shaking, weakness with loss of movement on one side of the body, tremor, slow movements, or stiffness - which may be symptoms of parkinsonism.

Uncommon side effects - affect 1-10 in 1,000 users:
- 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, serious state of confusion (delirium), fits - which may be symptoms of a medical condition called immune effector cell-associated neurotoxicity syndrome (ICANS).

Tell your doctor immediately if you have any of the side effects above, as you may need urgent medical treatment.

Additional side effects
Very common side effects - affect more than one in ten users:
- lack of energy
- high blood pressure
- decreased appetite
- constipation
- swollen ankles, arms, legs and face
- joint pain
- difficulty sleeping
- low number of white blood cells (neutrophils, leucocytes and lymphocytes), which can increase your risk of infection
- infections, including pneumonia or infections of the respiratory tract, mouth, skin, urinary tract or blood, which may be bacterial, viral or fungal
- laboratory test results showing low levels of antibodies, called immunoglobulins (hypogammaglobulinaemia) that are important in fighting infections
- laboratory test results showing decreased levels of calcium, sodium, magnesium, potassium, phosphate or albumin, which may cause fatigue, muscle weakness or cramps or an irregular heartbeat
- 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 side effects - affect 1-10 in 100 users:
- severe inflammation due to activation of your immune system, which could lead to serious damage in the body
- muscle pain
- abnormal body movements or lack of coordination
- uneven or irregular heartbeat
- fluid in the lungs
- low oxygen level in the blood, which may cause shortness of breath, confusion or drowsiness.

Rare side effects - affect 1-10 in 10,000 users:
- a new type of cancer beginning in a type of white blood cells called T cells (secondary malignancy of T cell origin).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

The following information is intended for doctors only.
Do not use this medicine after the expiry date which is stated on the cassette label and infusion bag label after 'EXP'.

Storage conditions: Store frozen in the vapour phase of liquid nitrogen (≤ -130°C). Do not thaw the medicine until it is ready to be used. Do not refreeze.

Do not use this medicine if the infusion bag is damaged or leaking.

6. Additional information

Each infusion bag of Abecma contains idecabtagene vicleucel cell dispersion at a batch-dependent concentration; the dispersion contains autologous T cells genetically modified to express an anti-BCMA chimeric antigen receptor (CAR-positive viable T cells). One or more infusion bags contain a total of 260 x 10^6 to 500 x 10^6 CAR-positive viable T cells.

- **In addition to the active ingredient, this medicine also contains:**
  Cryostor CS10 freeze media (containing DMSO), sodium chloride, sodium gluconate, sodium acetate trihydrate, potassium chloride, magnesium chloride, water for injection.

This medicine contains genetically modified human blood cells.

- **What the medicine looks like and contents of the pack**
  Abecma is a colourless cell dispersion for infusion, supplied in one or more infusion bags individually packed in metal cassettes. Each bag contains 10 mL to 100 mL of cell dispersion.
- **Registration holder's name and address:** Bristol-Myers Squibb (Israel) Ltd., 18 Aharon Bart St. P.O Box 3361, Kiryat Arye, Petach Tikva 4951448.
- **Manufacturer's name and address:**
  Bristol-Myers Squibb Company,
  Route 206 & Province Line Road, Princeton, New Jersey 08543, USA

Revised in October 2025

Registration number of the medicine in the Ministry of Health's National Drug Registry: 171-53-37039

המידע הבא מיועד לצוות רפואי בלבד:
المعلومات التالية معدّة للطاقم الطبيّ فقط:
The following information is intended for healthcare professionals only:

It is important that you read the entire content of this procedure prior to administering Abecma.

Precautions to be taken before handling or administering the medicinal product
- Abecma must be transported within the facility in closed, break-proof, leak-proof containers.
- This medicinal product contains human blood cells. Healthcare professionals handling Abecma must take appropriate precautions (wearing gloves and glasses) to avoid potential transmission of infectious diseases.

Preparation prior to administration
- Prior to Abecma infusion, it must be confirmed that the patient's identity matches the patient identifiers on the Abecma cassette(s), the infusion bag(s) and the release for infusion certificate (RfIC).
- The Abecma infusion bag must not be removed from the cassette if the information on the patient-specific label does not match the intended patient. The company must be contacted immediately if there are any discrepancies between the labels and the patient identifiers.
- If more than one infusion bag has been received for treatment, thaw each infusion bag one at a time. The timing of thaw of Abecma and infusion should be coordinated. The infusion start time should be confirmed in advance and adjusted for thaw so that Abecma is available for infusion when the patient is ready.

Thawing
- Remove the Abecma infusion bag from the cassette and inspect the infusion bag for any breaches of container integrity such as breaks or cracks before thawing. If the infusion bag appears to have been damaged or to be leaking, it should not be infused and should be disposed of according to local guidelines on handling of waste of human-derived material.
- Place the infusion bag inside a second sterile bag.
- Thaw Abecma at approximately 37°C using an approved thaw device or water bath until there is no visible ice in the infusion bag. Gently mix the contents of the bag to disperse visible clumps of cellular material. Small clumps of cellular material are expected in Abecma. Do not wash, spin down and/or resuspend Abecma in new media prior to infusion.

Administration
- Do NOT use a leukodepleting filter.
- Intravenous infusion of Abecma should only be administered by a healthcare professional experienced with immunosuppressed patients and prepared to manage anaphylaxis.
- Ensure that tocilizumab and emergency equipment are available prior to infusion and during the recovery period. In the exceptional case where tocilizumab is not available, ensure that suitable alternative measures to treat CRS instead of tocilizumab are available on-site.
- Central venous access may be utilised for the infusion of Abecma and is encouraged in patients with poor peripheral access.
- Before administration, it must be confirmed that the patient's identity matches the unique patient information on the Abecma infusion bag and accompanying documentation. The total number of infusion bags to be administered must also be confirmed with the patient specific information on the release for infusion certificate (RfIC).
- Prime the tubing of the infusion set with sodium chloride 9 mg/mL (0.9%) solution for injection prior to infusion. Infusion set with in-line filter (a non-leukodepleting filter with a pore size range of 170 to 260 µm) should be used for thawed products.
- Infuse Abecma within 1 hour from start of thaw as quickly as tolerated by gravity flow.
- After the entire content of the infusion bag is infused, rinse the tubing, inclusive of the in-line filter, with sodium chloride 9 mg/mL (0.9%) solution for injection at the same infusion rate to ensure as many cells as possible are infused into the patient.
- Follow the same procedure for all subsequent infusion bags for the identified patient.

Measures to take in case of accidental exposure
- In case of accidental exposure, local guidelines on handling of human-derived material must be followed. Work surfaces and materials which have potentially been in contact with Abecma must be decontaminated with appropriate disinfectant.

Precautions to be taken for the disposal of the medicinal product
Unused medicinal product and all material that has been in contact with Abecma (solid and liquid waste) must be handled and disposed of as potentially infectious waste in accordance with local guidelines on handling of human-derived material.