Package leaflet: Information for the patient

TECARTUS suspension for intravenous infusion
brexucabtagene autoleucel (CAR+ viable T cells)

Read all of this leaflet carefully before you are administered TECARTUS because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- 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 hospital.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TECARTUS is and what it is used for
2. What you need to know before you are administered TECARTUS
3. How TECARTUS is administered
4. Possible side effects
5. How to store TECARTUS
6. Contents of the pack and other information

1. What TECARTUS is and what it is used for

TECARTUS is a cell, tissue and gene therapy product (CTGTP) used for treating mantle cell lymphoma in adults. It is used when other medicines have stopped working for you (relapsed or refractory mantle cell lymphoma). TECARTUS is made specially for you from your own white blood cells that have been modified and is known as brexucabtagene autoleucel.

Mantle cell lymphoma is a cancer of a part of the immune system (the body's defences). It affects a type of white blood cell called B-lymphocytes. In mantle cell lymphoma, B-lymphocytes grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood.

How TECARTUS works

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

2. What you need to know before you are administered TECARTUS

You are not to be administered TECARTUS
- if you are allergic to any of the ingredients of TECARTUS (listed in section 5). If you think you may be allergic, ask your doctor for advice.
- if you can't receive the medicine to reduce the number of white blood cells in your blood (*lymphodepleting chemotherapy*) (see also section 3, How TECARTUS is administered).

Warnings and precautions

TECARTUS is made from your own white blood cells and must only be administered to you (*autologous use*).

Tests and checks

Before you are administered TECARTUS your doctor will:
- Check your lungs, heart, kidney and blood pressure.
- Look for signs of infection or inflammation; and decide whether you need to be treated before you are administered TECARTUS.
- Check if your cancer is getting worse.
- Look for signs of graft-versus-host disease that can happen after a transplant. This happens when transplanted cells attack your body, causing symptoms such as rash, nausea, vomiting, diarrhoea and bloody stools.
- Check your blood for uric acid and for how many cancer cells there are in your blood. This will show if you are likely to develop a condition called *tumour lysis syndrome.* You may be administered medicines to help prevent the condition.
- Check for hepatitis B, hepatitis C or HIV infection.
- Check if you had a vaccination in the previous 6 weeks or are planning to have one in the next few months.
- Check if you have previously received a treatment that attaches to the protein called CD19.

In some cases, it might not be possible to go ahead with the planned treatment with TECARTUS. If TECARTUS infusion is delayed for more than 2 weeks after you have received lymphodepleting chemotherapy you may have to receive more chemotherapy (see also section 3, How TECARTUS is administered).

After you have been administered TECARTUS

Tell your doctor or nurse immediately or get emergency help right away if you have any of the following:
- Chills, extreme tiredness, weakness, dizziness, headache, cough, shortness of breath, rapid or irregular heartbeat, severe nausea, vomiting, or diarrhoea which may be symptoms of a condition known as *cytokine release syndrome.* Take your temperature twice a day for 3 to 4 weeks after treatment with TECARTUS. If your temperature is high, see your doctor immediately.
- Fits, shaking, or difficulty speaking or slurred speech, loss of consciousness or decreased level of consciousness, confusion and disorientation, loss of balance or coordination.
- Fever (e.g. temperature above 38°C), which may be a symptom of an infection.
- Extreme tiredness, weakness and shortness of breath, which may be symptoms of a lack of red blood cells.
- Bleeding or bruising more easily, which may be symptoms of low levels of cells in the blood known as platelets.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse.

Your doctor will regularly check your blood counts as the number of blood cells and other blood components may decrease.

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

Children and adolescents

TECARTUS must not be used in children and adolescents below 18 years of age.

Other medicines and TECARTUS

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Before you are administered TECARTUS tell your doctor or nurse if you are taking any medicines that weaken your immune system such as corticosteroids, since these medicines may interfere with the effect of TECARTUS.

In particular, you must not be administered certain vaccines called live vaccines:
- In the 6 weeks before you are administered the short course of lymphodepleting chemotherapy to prepare your body for the TECARTUS cells.
- During TECARTUS 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 have a baby, ask your doctor for advice before being administered TECARTUS. This is because the effects of TECARTUS in pregnant or breast-feeding women are not known, and it may harm your unborn baby or your breast-fed child.
- If you are pregnant or think you may be pregnant after treatment with TECARTUS, talk to your doctor immediately.
- You will be administered a pregnancy test before treatment starts. TECARTUS can only be administered if the results show you are not pregnant.

Discuss pregnancy with your doctor if you have received TECARTUS.

Driving and using machines

TECARTUS can cause problems such as altered or decreased consciousness, confusion and seizures (fits) in the 8 weeks after it is administered.

Do not drive, use machines, or take part in activities that need you to be alert for at least 8 weeks after your TECARTUS treatment or until your doctor tells you that you have completely recovered.

TECARTUS contains sodium, dimethylsulfoxide (DMSO) and residual gentamicin

TECARTUS contains 300 mg sodium (main component of cooking/table salt) in each infusion bag. This is equivalent to 15% of the recommended maximum daily dietary intake of sodium for an adult. It also contains DMSO and residual gentamicin which may cause severe hypersensitivity reactions.

3. How TECARTUS is administered

TECARTUS will always be administered to you by a healthcare professional.

- Since TECARTUS is made from your own white blood cells, your cells will be collected from you to prepare TECARTUS. Your doctor will take some of your blood using a catheter placed in your vein (a procedure call *leukapheresis*). Some of your white blood cells are separated from your blood and the rest of your blood is returned to your vein. This can take 3 to 6 hours and may need to be repeated.
- Your white blood cells are sent away to a manufacturing center to make your TECARTUS. It usually takes about 2 to 3 weeks to make TECARTUS but the time may vary.

Medicines administered before TECARTUS treatment

A few days before you receive TECARTUS, you will be administered lymphodepleting chemotherapy, which will allow the modified white blood cells in TECARTUS to multiply in your body when the CTGTP is administered to you.

During the 30 to 60 minutes before you are administered TECARTUS you may be administered other medicines. This is to help prevent infusion reactions and fever. These other medicines may include:
- Paracetamol.
- An antihistamine such as diphenhydramine.

How you are administered TECARTUS

TECARTUS will always be administered to you by a doctor in a qualified treatment centre.

- TECARTUS is administered in a single dose.
- Your doctor or nurse will give you a single infusion of TECARTUS through a catheter placed into your vein (*intravenous infusion*) over about 30 minutes.
- TECARTUS is the genetically modified version of your white blood cells. Your healthcare professional handling the treatment will therefore take appropriate precautions (wearing gloves and glasses) to avoid potential transmission of infectious diseases and will follow local guidelines on handling of waste of human-derived material to clean up or dispose of any material that has been in contact with it.

After you are administered TECARTUS

- You must stay close to the hospital where you were treated for at least 4 weeks after TECARTUS treatment. Your doctor will recommend that you return to the hospital daily for at least 7 days or that you stay at the hospital as an in-patient for the first 7 days after TECARTUS treatment. This is so your doctor can check if your treatment is working and help you if you have any side effects.

If you miss any appointments, call your doctor or your treatment centre as soon as possible to reschedule your appointment.

4. Possible side effects

Like all medicines, TECARTUS can cause side effects, although not everybody gets them. Do not try to treat your side effects on your own.

TECARTUS can cause side effects that may be serious or life-threatening. **Get urgent medical attention** if you get any of the following side effects after the TECARTUS infusion.

Very common: may affect more than 1 in 10 people

– Fever, chills, reduced blood pressure which may cause symptoms such as dizziness, lightheadedness, fluid in the lungs, which may be severe and can be fatal (all symptoms of a condition called *cytokine release syndrome*).
– Loss of consciousness or decreased level of consciousness, confusion or memory loss due to disturbances of brain function, difficulty speaking or slurred speech, involuntary shaking (*tremor*), fits (*seizures*), sudden confusion with agitation, disorientation, hallucination or irritability (*delirium*).
– Fever, chills, which may be signs of an infection.

Other possible side effects

Other side effects are listed below. If these side effects become severe or serious, tell your doctor immediately.

Very common: may affect more than 1 in 10 people

- Abnormally low number of white blood cells, which may increase your risk of infection.
- Low number of cells that help clot the blood *(thrombocytopenia)*,: symptoms can include excessive or prolonged bleeding or bruising.
- High blood pressure.
- Decrease in the number of red blood cells (cells that carry oxygen): symptoms can include extreme tiredness with a loss of energy.
- Extreme tiredness.
- Fast or slow heartbeat.
- Decrease of oxygen reaching body tissues: symptoms can include changes to the colour of your skin, confusion, rapid breathing.
- Shortness of breath, cough.
- Nausea, constipation, diarrhoea, abdominal pain, vomiting, difficulty swallowing.
- Muscle pain, joint pain, bone pain, pain in the extremities of the body.
- Lack of energy or strength, muscular weakness, difficulty moving, muscle spasm.
- Headache.
- Kidney problems causing your body to hold onto fluid, build-up of fluids in tissue *(oedema)* which can lead to weight gain and difficulty in breathing, decrease output of urine.
- High levels of uric acid seen in blood tests.
- Low levels of sodium, phosphate, potassium or calcium seen in blood tests.
- Decreased appetite, sore mouth.
- Difficulty sleeping, anxiety.
- Swelling in the limbs, fluid around the lungs *(pleural effusion)*.
- Skin rash.
- Low levels of immunoglobulins seen in blood test, which may lead to infections.
- Increase in liver enzymes seen in blood tests.
- Blood clots: symptoms can include pain in the chest or upper back, difficulty breathing, coughing up blood or cramping pain, swelling in a single leg, warm and darkened skin around the painful area.
- Nerve pain.

Common: may affect up to 1 in 10 people

- Low levels of albumin seen in blood tests.
- Excessive bleeding.
- Irregular heartbeat *(arrhythmia)*.
- Loss of control of body movements.
- Dry mouth, dehydration.
- Breathlessness *(respiratory failure)*.
- Difficulty breathing which makes you unable to speak in full sentence, cough due to fluid in the lungs.
- Increase of the pressure inside your skull.
- Infusion related reactions: symptoms including dizziness or fainting, flushing, rash, itching, fever, shortness of breath or vomiting, abdominal pain, and diarrhoea.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of TECARTUS.

5. Contents of the pack and other information

What TECARTUS contains

The active substance is brexucabtagene autoleucel. Each patient-specific single infusion bag contains a suspension of anti-CD19CAR-positive viable T cells in approximately 68 mL for a target dose of 2×10^6 anti-CD19 CAR-positive viable T cells/kg.

The other ingredients (excipients) are: Cryostor CS10 (contains DMSO), sodium chloride, human albumin.

TECARTUS contains genetically modified human blood cells.

What TECARTUS looks like and contents of the pack

TECARTUS is a clear to opaque, white to red suspension for infusion, supplied in an infusion bag individually packed in a metal cassette. A single infusion bag contains approximately 68 mL of cell suspension.

Product Owner
Kite Pharma, Inc.
2400 Broadway
Santa Monica, CA 90404
USA

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