

Consumer Medicine Information

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine Release Syndrome (CRS), including fatal or life threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life threatening CRS with tocilizumab or tocilizumab and corticosteroids.

This leaflet provides important information about using TECARTUS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TECARTUS.**

Where to find information in this leaflet:

1. Why am I given TECARTUS?
2. What should I know before I am given TECARTUS?
3. What if I am taking other medicines?
4. How am I given TECARTUS?
5. What should I know after I am given TECARTUS?
6. Are there any side effects?
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1. Why am I given TECARTUS?**TECARTUS also known as**

brexucabtagene autoleucel is a type of medicine called a “genetically modified cell therapy”. TECARTUS is made specially for you as a single administration of your own modified white blood cells. It is given by a drip (*infusion*) into a vein (*intravenously*).

TECARTUS is used to treat mantle cell lymphoma in adults. Mantle cell lymphoma is a cancer that affects part of the immune system (the lymph tissue). It affects a type of white blood cell called B lymphocytes. Mantle cell lymphoma is a disease where B lymphocytes grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood. TECARTUS is used to treat this condition when other available medicines have stopped working for you.

2. What should I know before I am given TECARTUS?**Warnings and Precautions****Do not use TECARTUS if:**

- You are allergic to brexucabtagene autoleucel, or any of the ingredients listed at the end of this leaflet.

Tell your doctor (or your doctor will check) if you:

- have problems with your nervous system (such as fits, stroke, or memory loss).
- have kidney problems.
- have low blood cell levels (blood counts).
- have any problems with your lungs, heart or blood pressure (low or high).
- have had a stem cell transplant in the last 4 months
- have signs or symptoms of graft versus host disease. This happens when transplanted cells attack your body, causing symptoms such as rash, nausea, vomiting, diarrhoea and bloody stools.
- notice the symptoms of your cancer are getting worse. If you have lymphoma this might include fever, feeling weak, night sweats, sudden weight loss

- have an infection. The infection will be treated before the TECARTUS infusion.
- have had hepatitis B, hepatitis C or human immunodeficiency virus (HIV) infection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Plan to stay within proximity (i.e. within 2 hours) of the hospital where you will be treated for at least 4 weeks after you have been given TECARTUS.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 feeding child.

You will be given a pregnancy test before treatment starts. TECARTUS should only be given if the results show you are not pregnant.

If you are pregnant or think you may be pregnant after treatment with TECARTUS, talk to your doctor immediately.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Before you are given 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 given certain vaccines called live vaccines:

- In the 6 weeks before you are given the short course of chemotherapy (called 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TECARTUS.