Information for Patients

Neurologic Adverse Reactions

The following may be symptoms of ICANS:

- Confusion
- Being less alert (decreased consciousness)
- Difficulty speaking or slurred speech
- Shaking (tremor)
- Feeling anxious
- Feeling dizzy
- Headache

▼ This material fulfils a condition of the lisocabtagene maraleucel marketing authorisation and has been approved by Saudi FDA Jul 2026

For reporting any suspected adverse reactions via the national reporting system :
Bristol Myers Squibb, Saudi Arabia :
At: medinfo.SaudiArabia@bms.com
or call: 800 844 7710

OR

The National Pharmacovigilance Centre (NPC)
Saudi Food and Drug Authority (SFDA):
SFDA call centre: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Local Approval Number:
2009-SA-2600003
Saudi FDA approval Date:
Jul 2026

IMPORTANT SAFETY INFORMATION FOR PATIENTS

BREYANZI™ ▼
(lisocabtagene maraleucel)

Patient Card

The document is approved by The Executive Directorate of Pharmacovigilance, SFDA.

▼ **Have this card with you at all times. Show it to any doctor/healthcare provider who sees you, including in an emergency.**

- Tell any healthcare provider who sees you that you are being treated with lisocabtagene maraleucel.
- For at least 4 weeks after receiving lisocabtagene maraleucel, you should plan to stay close to the location where you received treatment. Your doctor may recommend you stay longer to make sure the care you get after your treatment meets your individual needs.
- Do not drive, use machines, or take part in activities that need you to be alert for at least 8 weeks after treatment. lisocabtagene maraleucel can make you sleepy, decrease awareness, and cause confusion and seizures (fits). Based on your individual needs, your doctor may advise you to wait longer before driving.

Bristol Myers Squibb®

Local Approval Number:
2009-SA-2600003
Saudi FDA approval Date:
Jul 2026

I have been treated with lisocabtagene maraleucel

Important Contact Information

My Name: _____

Name of lisocabtagene maraleucel Treating Physician (PRINT): _____

Office/Hospital Phone Number: _____

After-hours Phone Number: _____

Hospital Name: _____

Date of lisocabtagene maraleucel Infusion (DD/MM/YYYY): _____

Batch Number (PRINT): _____

Information for the Healthcare Provider

This patient has received lisocabtagene maraleucel chimeric antigen receptor (CAR)-positive T-cell therapy, a cluster of differentiation (CD)19-directed genetically modified autologous cell-based product.

Following treatment with lisocabtagene maraleucel, cytokine release syndrome (CRS) and/or neurologic toxicities, including immune effector cell-associated neurotoxicity syndrome (ICANS), may occur, which may be fatal or life threatening. Cytokine release syndrome (CRS) may involve any organ system.

Contact patient's lisocabtagene maraleucel treating physician immediately for further information.

Please see lisocabtagene maraleucel's Summary of Product Characteristics and Package leaflet which can be found with your health care provider.

Information for Patients

lisocabtagene maraleucel may cause side effects that are severe or life-threatening. Call your lisocabtagene maraleucel treating physician or go to the emergency room/department immediately if any of the following symptoms appear:

Cytokine Release Syndrome (CRS)

- Fever
- Chills or shaking
- Feeling tired
- Fast or uneven heartbeat
- Feeling light-headed and short of breath