LIBMELDY® 2-10 × 10^6 cells/mL dispersion for infusion

atidarsagene autotemcel ($CD34^+$ cells)

Patient Alert Card

Have this card with you at all times.

Tell all healthcare providers that you have been treated with Libmeldy and show them this card.

My name is: _____

I have been treated with Libmeldy, a gene therapy medicinal product for metachromatic leukodystrophy.

Medicinal product lot #: _____

Date of treatment: _____

Libmeldy treating doctor: _____

Doctor contact details: _____

By reporting side effects, you can help provide more information on the safety of this medicine. When reporting possible side effects, include the medicinal product lot number.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in the package leaflet. See the back of this card for ways to report side effects.

This document is approved by the Pharmacovigilance Department, at SFDA.

Important information for healthcare professionals

Before providing any treatment, please contact the treating physician on the front of this card

- The holder of this card has received Libmeldy, an autologous gene therapy medicinal product, and should not donate blood, organs, tissues, and cells for transplantation.
- There is a possibility of false positive results on certain commercial HIV tests.
- For additional information about Libmeldy, see the Summary of Product Characteristics on Saudi Vigilance Information System website: https://sdi.sfda.gov.sa/.

Reporting of adverse reactions/side effects

- Report any suspected adverse reactions via the National Pharmacovigilance Centre (NPC) at the Saudi Food and Drug Authority (SFDA) Call Center: 19999, E-mail: npc.drug@sfda.gov.sa, Website: https://ade.sfda.gov.sa/
- Also report any suspected adverse reactions involving Libmeldy to Orchard Therapeutics by email to drugsafety@orchard-tx.com and Cigalah by email to drug-safety@cigalah.com.sa.
  Include the medicinal product lot number found on this card.