Additional Resources

For additional information, please refer to the Summary of Product Characteristics (SmPC) or contact AM Mangion Medical Information by using one of the following methods:

Phone (24/7): 00356 2397 6888

Email: medicalaffairs@ammangion.com

Reporting of side effects:

To report Suspected Adverse Reactions, contact AM Mangion on the following:

Phone (24/7): 00356 2397 6333

Email: pv@ammangion.com

Address: AM Mangion Ltd, Mangion Building, N/S Off Valletta Road, Luqa, LQA 6000, MALTA

If you get any side effects, talk to your doctor or nurse. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine

Date of preparation: October 2021. Date of MA approval: April 2022
CP-294284/DAR/0222/004

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DARZALEX® (daratumumab)

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DARZALEX® (daratumumab)

Understanding & Mitigating daratumumab Interference with Blood Compatibility Testing – Guide for Blood Banks

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daratumumab Interference Mitigation Methods

REMEMBER

daratumumab-treated patients may show pan-reactivity in Indirect Antiglobulin Test (IAT)

daratumumab interference mitigation methods

Treat reagent RBCs with DTT or locally validated methods

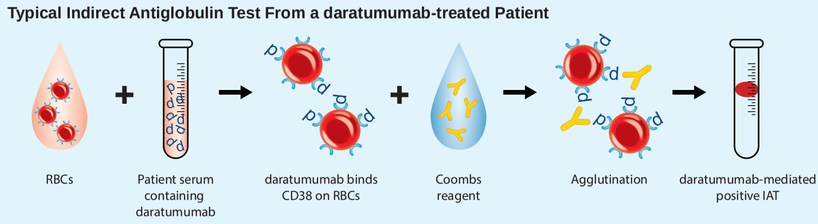
OR

Genotype

ID CARD **If available, refer to the patient's ID card for their blood type and antibody screen results conducted prior to initiation of daratumumab treatment.**

DTT, dithiothreitol; RBCs, red blood cells.

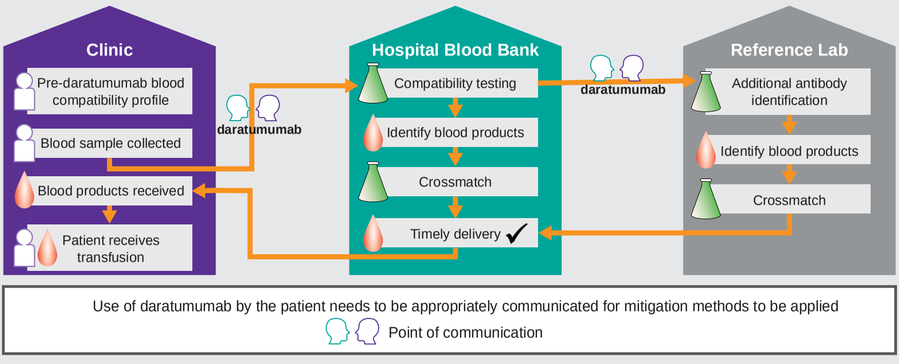
Daratumumab Results in a Positive Indirect Antiglobulin Test which may persist for up to 6 months after the last product's infusion



IAT, indirect antiglobulin test; RBCs, red blood cells.

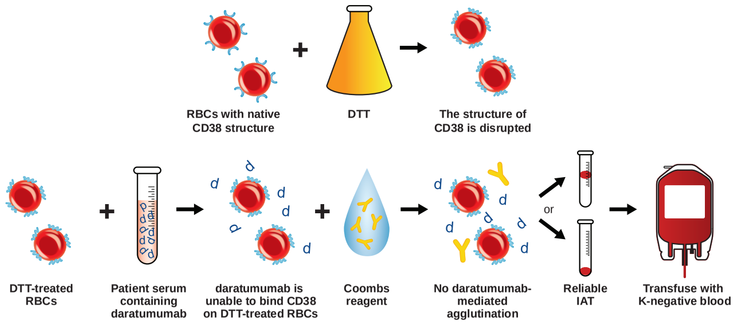
- daratumumab is a human monoclonal antibody for the treatment of multiple myeloma or AL amyloidosis[2]
- daratumumab binds to CD38,[1] a protein that is expressed at low levels on red blood cells (RBCs)[3-5]
- daratumumab binding to RBCs may mask the detection of antibodies to minor antigens. This interferes with compatibility tests, including the antibody screening and crossmatching[1]

Help Prevent Delays by Applying Mitigation Methods



- If steps are not taken to mitigate daratumumab interference, delays in the release of blood products for transfusion may occur
- Blood products for transfusion can be identified for daratumumab-treated patients using protocols available in the literature[1,6] or by using genotyping[7]
- Mitigation methods should be used until pan-agglutination is no longer observed

Treat Reagent RBCs With DTT or Locally Validated Method



DDT, dithiothreitol; IAT, indirect antiglobulin test; RBC, red blood cells.

- Treat reagent RBCs with dithiothreitol (DTT) to disrupt daratumumab binding, thus allowing antibody screening or crossmatching to be performed; the protocol can be found in Chapuy et al[1]. Alternative locally validated methods can also be used
- Blood products for transfusion were identified for daratumumab-treated patients, after using DTT-treated reagent RBCs for antibody screening[1]
- Since the Kell blood group system is also sensitive to DTT treatment,[8] K-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs

Daratumumab Interference Is Clinically Manageable

- To date, no clinically significant hemolysis has been observed in patients receiving daratumumab, and no transfusion reactions have occurred in patients requiring transfusions (data on file)
- daratumumab does not interfere with identification of ABO/RhD antigens[1]
- If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices[6]
- A patient's compatibility profile, determined prior to their first dose of daratumumab, is recorded on the patient's ID card