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
- If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices⁶
- · A patient's compatibility profile, determined prior to their first dose of daratumumab, is recorded on the patient's ID card For additional information, please refer to the Summary of Product Characteristics (SmPC) or contact Janssen Medical Information by using one of the following methods:

 Phone: 00356 2397 6000

Email: pv@ammangion.com Search: www.ammangion.com.mt

To report SUSPECTED ADVERSE REACTIONS, contact Janssen on the following: Phone (24/7): 00356 2397 6333

Email: http://pww.emangion.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 on www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.





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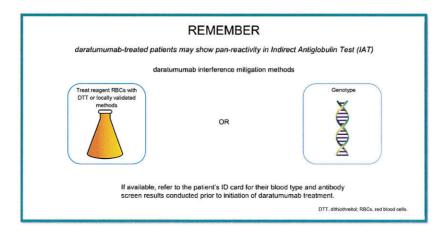
References



Understanding & Mitigating daratumumab Interference with Blood Compatibility Testing

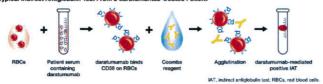


daratumumab Interference Mitigation Methods



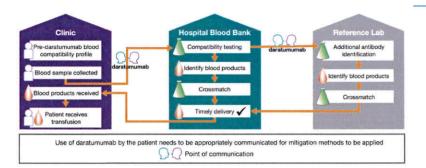
daratumumab Results in a Positive Indirect Antiglobulin Test which may persist for up to 6 months after the last product's infusion

Typical Indirect Antiglobulin Test From a daratumumab-treated Patient



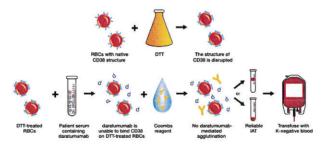
- . daratumumab is a human monoclonal antibody for the treatment of multiple myeloma
- daratumumab binds to CD38,¹ a protein that is expressed at low levels on red blood cells (RBCs)³⁻⁵
- daratumumab binding to RBCs may mask the detection of antibodies to minor antigens. This interferes with compatibility tests, including the antibody screening and crossmatching¹

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 genotyping⁷
- 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 deraturnumab binding, thus allowing anlibody screening or crossmatching to be performed; the protocol can be found in Chapuy et al. 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.
- Since the Kell blood group system is also sensitive to DTT treatment.⁵ K-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs