Daratumumab interference is clinically manageable

- There is a theoretical risk of haemolysis and therefore, continuous monitoring for this safety signal will be performed in clinical studies and post marketing safety data.[8]
- 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.[5]
- In the event of a planned transfusion, Healthcare Professionals should notify blood transfusion centres about the interference with indirect antiglobulin tests.
- All patients should be typed and screened prior to initiating treatment with daratumumab; alternatively, phenotyping may also be considered. The patient's compatability profile, should be recorded on the patient's ID card.
- The Healthcare Professionals should provide a patient ID card to their patients and advise them to consult the package leaflet.
- The patient should be advised to carry the patient ID card for six months after stopping treatment as daratumumab-mediated positive indirect Coombs test (interfering with cross-matching of blood) may persist for up to six months after the last daratumumab infusion.

Additional Resources

For additional information, please contact Janssen Medical Information by using one of the following methods:

Phone: 1800 709 122 | **Email:** medinfo@its.jnj.com | **Search:** www.janssen.com/ireland/contact-us

Reporting of Adverse Events

Healthcare professionals are asked to report any suspected adverse events via HPRA Pharmacovigilance: Website www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC on 1800 709 122 or at dsafety@its.jnj.com.

In order to improve the traceability of Darzalex, the tradename and the batch number of the administered product should be clearly recorded in the patient file and when reporting an Adverse Event.

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Date of preparation: April 2022 | CP-305883

DARZALEX® daratumumab

REFERENCES:

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2. Alberiz I, Demir O, Türker-Sener L, Yalcintepe L, Nurten R, Bermek E. Erythrocyte CD38 as a prognostic marker in cancer. Hematology. 2007;12(5):409-414.
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4. Zocchi E, Franco L, Guida L, *et al.* A single protein immunologically identified as CD38 displays NAD+glycohydrolase, ADP-ribosyl cyclase and cyclic ADP-ribose hydrolase activities at the outer surface of human erythrocytes. Biochem Biophys Res Commun. 1993;196(3):1459-1465.
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6. Hannon JL, Clarke G. Transfusion management of patients receiving daratumumab therapy for advanced plasma cell myeloma. Transfusion. 2015;55(11):2770.
7. Westhoff CM, Reid ME. Review: the Kell, Duffy, and Kidd blood group systems. Immunohematology. 2004;20(1):37-49.
8. DARZALEX® Summary of Product Characteristics, available from www.medicines.ie.

DARZALEX®
daratumumab

Important risk minimisation information regarding interference with Blood Compatibility Testing: DARZALEX® (daratumumab) Card for Haematology/Transfusion Laboratory

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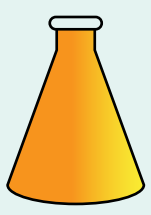
Daratumumab Interference Mitigation Methods

REMEMBER

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

daratumumab interference mitigation methods

Treat reagent RBCs with DTT



OR

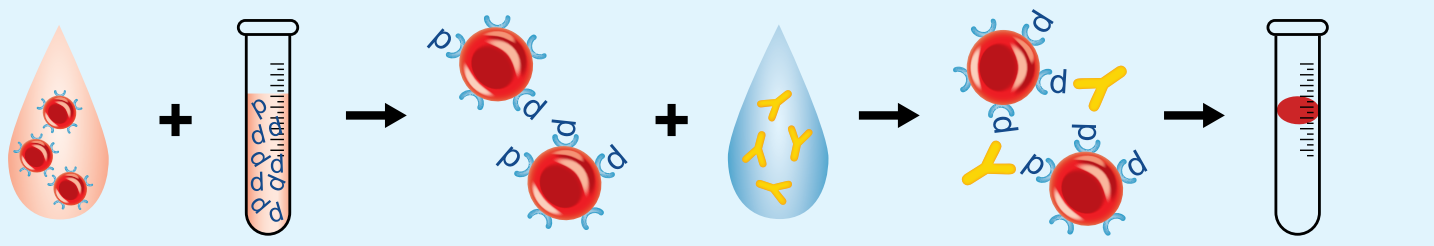
Genotype

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[5]

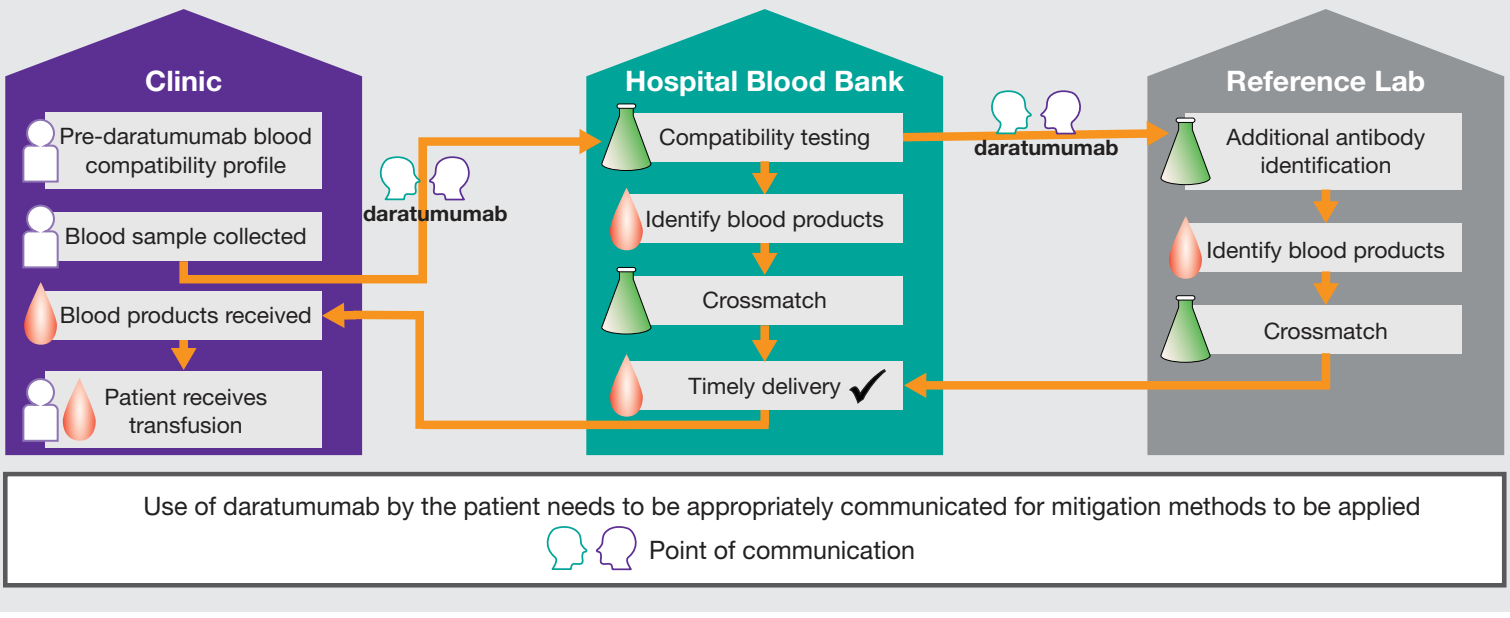
Typical Indirect Antiglobulin Test From a daratumumab-treated Patient



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

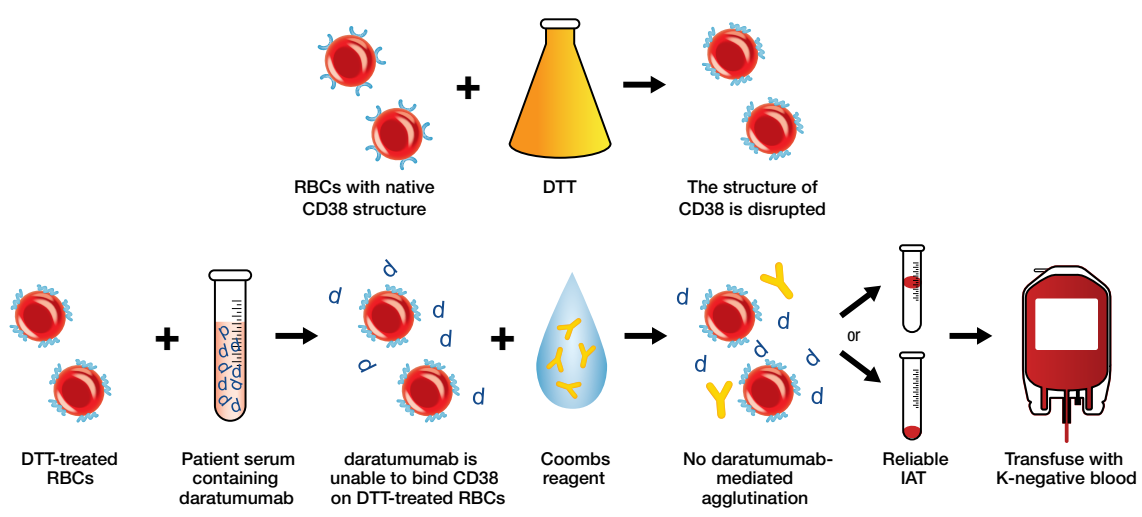
- Daratumumab is a human monoclonal antibody for the treatment of multiple myeloma (solution for infusion and solution for injection) or AL Amyloidosis (solution for injection)[8]
- Daratumumab binds to CD38,[1] a protein that is expressed at low levels on red blood cells (RBCs)[2-4]
- Daratumumab binding 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[1,5] or by using genotyping[6]
- Mitigation methods should be used until pan-agglutination is no longer observed

Treat Reagent RBCs With DTT or Locally Validated Methods



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]
- 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,[7] K-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs