DARATUMUMAB

important information on safety and risk minimization of daratumumab and interference with blood compatability testing

Healthcare Professional Card

References

1. Daratumumab Summary of Product Characteristics, Janssen-Cilag International NV, Beerse, Belgium.
2. Chapuy CI, Nicholson RT, Aguad MD, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55(6Pt 2):1545-1554.
3. Albeniz I, Demir O, Turker-Sener L, Yalcintepe L, Nurten R, Bermek E. Erythrocyte CD38 as a prognostic marker in cancer. *Hematology*. 2007;12(5):409-414.
4. Mehta K, Shahid U, Malavasi F. Human CD38, a cell-surface protein with multiple functions. *FASEB J*. 1996;10(12):1408-1417.
5. 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.
6. Oostendorp M, Lammerts van Bueren JJ, Doshi P, et al. When blood transfusion medicine becomes complicated due to interference by monoclonal antibody therapy. *Transfusion*. 2015;55(6 Pt 2):1555-1562.
7. Hannon JL, Clarke G. Transfusion management of patients receiving daratumumab therapy for advanced plasma cell myeloma. *Transfusion*. 2015;55(11):2770.

This document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA) September 2024, Version 1.0

DARATUMUMAB

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

To Ensure Timely Transfusions

REMEMBER

If a patient who received daratumumab requires a transfusion:

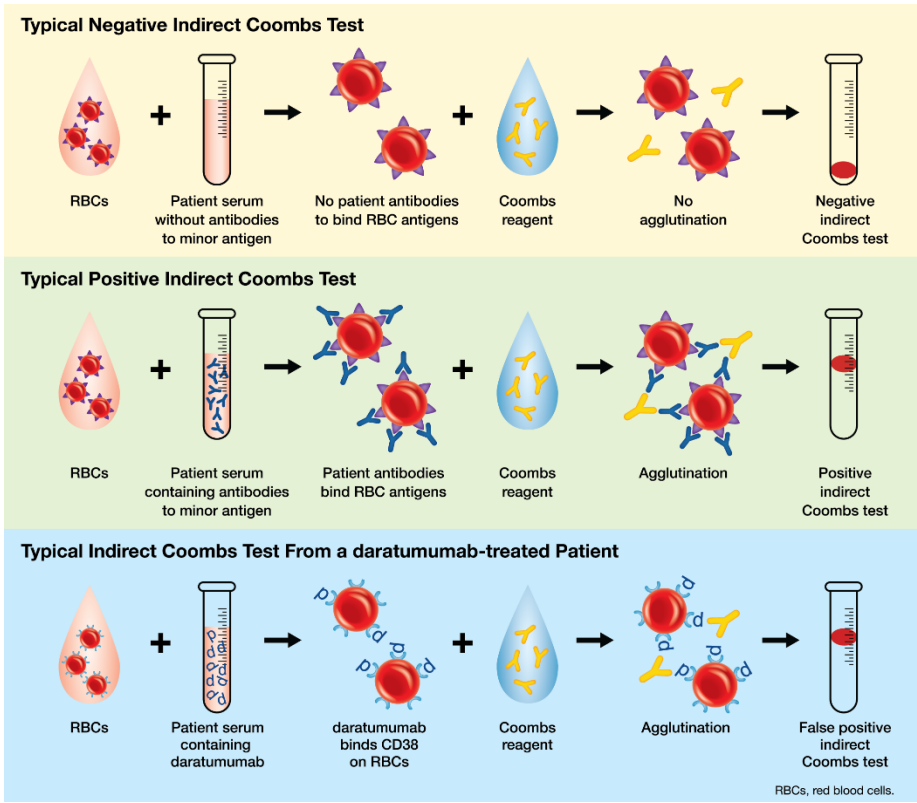
- Type and screen patients prior to starting daratumumab. Inform the blood bank that your patient has been treated with daratumumab which interferes with indirect antiglobulin tests
- Ensure that your patient's blood sample is identified as containing daratumumab. If a transfusion is planned, notify the blood transfusion center about any interference with indirect antiglobulin tests
- Double-check standing orders for transfusions to determine if your patient received daratumumab within the last year, and are instructed to carry this for 6 months after stopping treatment.
- Ensure patients are given a Patient ID Card for daratumumab and provide your patient's pre-daratumumab compatibility profile, if available, to the blood bank. Ask your patient to tell their other HCPs that they have received daratumumab, particularly before a transfusion

ID CARD

daratumumab

This document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA) September 2024, Version 1.0

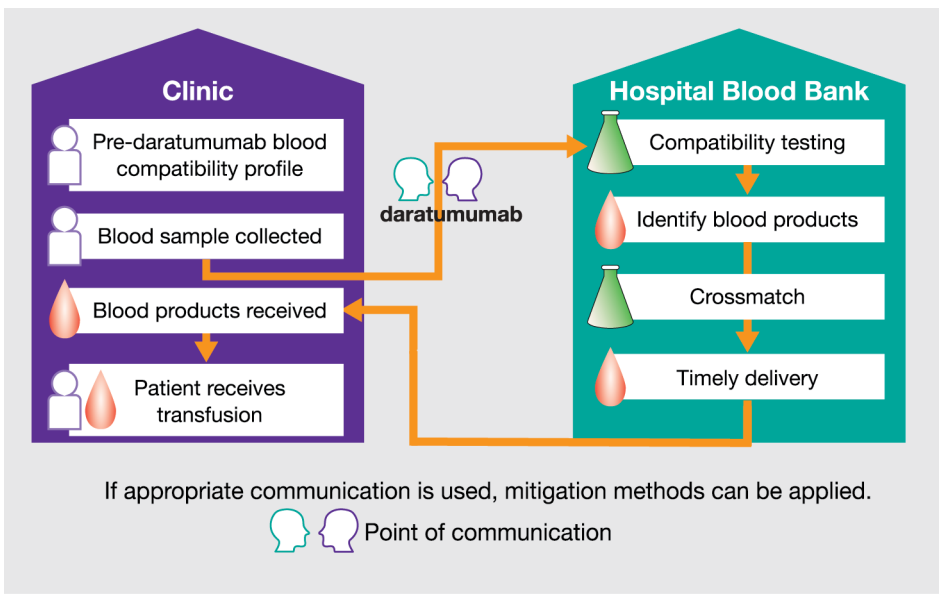
Daratumumab Results in a False Positive Indirect Coombs Test



- daratumumab is a human monoclonal antibody for the treatment of multiple myeloma or AL Amyloidosis[1]
- daratumumab binds to CD38,[2] 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 in the patient's serum. This interferes with blood bank compatibility tests, including the antibody screening and crossmatching[2] (both indirect Coombs tests) that are part of a routine pretransfusion work up

This document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA) September 2024, Version 1.0

Help Prevent Blood Transfusion Delays



- Blood compatibility testing can still be performed on daratumumab-treated patients
- Blood products for transfusion can be identified for daratumumab-treated patients using protocols available in the literature[2,6], or locally validated methods. Genotyping may also be considered
- **To ensure that your patient receives a timely transfusion, type and screen patients prior to starting daratumumab and inform the blood bank that they will receive a sample from a daratumumab-treated patient. Phenotyping may be considered prior to starting daratumumab treatment as per local practice.**

This document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA) September 2024, Version 1.0

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 RBC and whole blood transfusions. In the current post marketing safety data, clinically significant hemolysis has not been observed (data on file)
- In the event of a planned transfusion, the healthcare professional should notify blood transfusion centres that the patient is receiving daratumumab and therefore there is interference with indirect antiglobulin tests.
- daratumumab does not interfere with identification of ABO/RhD antigens[2]
- If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices[6]
- Once treatment with daratumumab is discontinued, pan-agglutination may persist; the duration of this effect varies from patient to patient, but may persist for up to 6 months after the last daratumumab infusion[6]. Therefore, patients should carry their Patient ID Card for 6 months after the treatment has ended

Additional Resources

For full prescribing information, please refer to the datasheet or contact Johnson & Johnson Middle East FZ-LLC (Riyadh) Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30, Olaya towers. Office Tel 00966-11-4339133 , Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia

Adverse events reporting guidance:

SFDA (National Pharmacovigilance center) Email: npc.drug@sfda.gov.sa , Telephone: 19999 , Online: http://ade.sfda.gov.sa

To report Adverse Events/Product Complaint or any Medical Information Inquiries,

please contact us at: Email: GCC-PV2@its.jnj.com ,

Hotline: 00966540015811

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.