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

Double-check standing orders for transfusions to determine if your patient received daratumumab within the last year

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

DARZALEX®
(daratumumab)

Date of preparation: October 2021, Date of HA approval: April 2022
CP-294292/DAR/0222/005

Janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

DARZALEX®
(daratumumab)

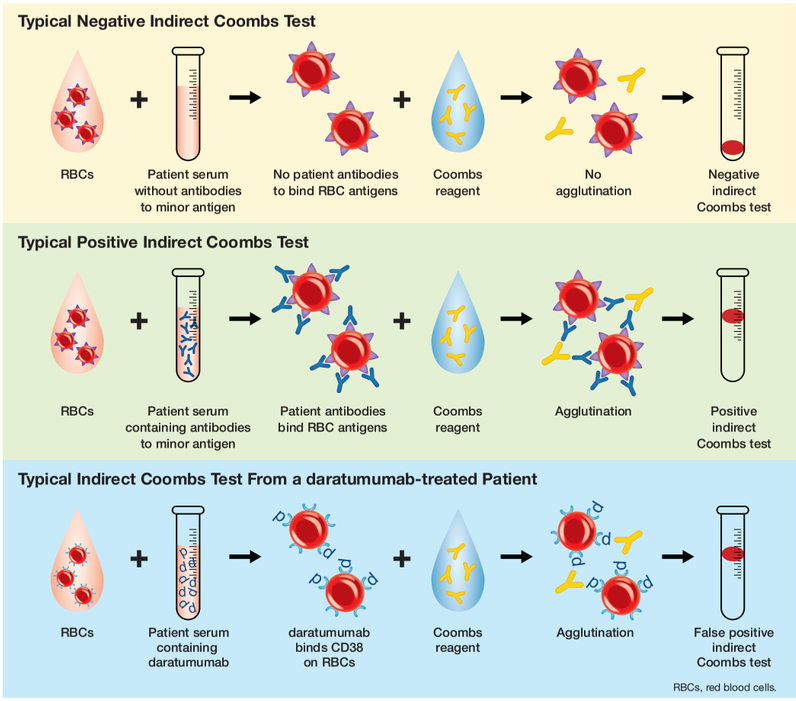
Understanding daratumumab Interference with Blood Compatibility Testing – Guide for HCPs

Janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

References

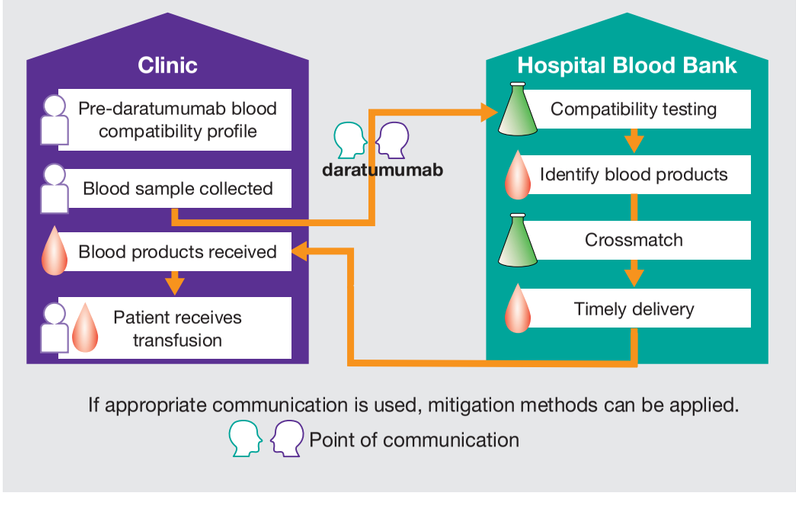
1. Daratumumab Summary of Product Characteristics, Janssen-Cilag International NV, Beerse, Belgium.
2. Chapuy CI, Nicholson RT, Aguad MD, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55(6Pt 2):1545-1554.
3. Albeniz I, Demir O, Türker-Sener L, Yalcintepe 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.

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

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.**

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 (data on file)
- 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
- Patients should be advised to consult the Patient Information Leaflet (PIL) for further information

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