This guide should be read in conjunction with the Summary of Product Characteristics (SmPC).

This guide has been approved by the HPRA
EM-196584 | Date of approval: September 2026

Important risk minimisation information regarding interference with Blood Compatibility Testing:

DARZALEX® (daratumumab) Healthcare Professional Card

Johnson&Johnson

References

1. DARZALEX® Summary of Product Characteristics, available from www.medicines.ie.
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.

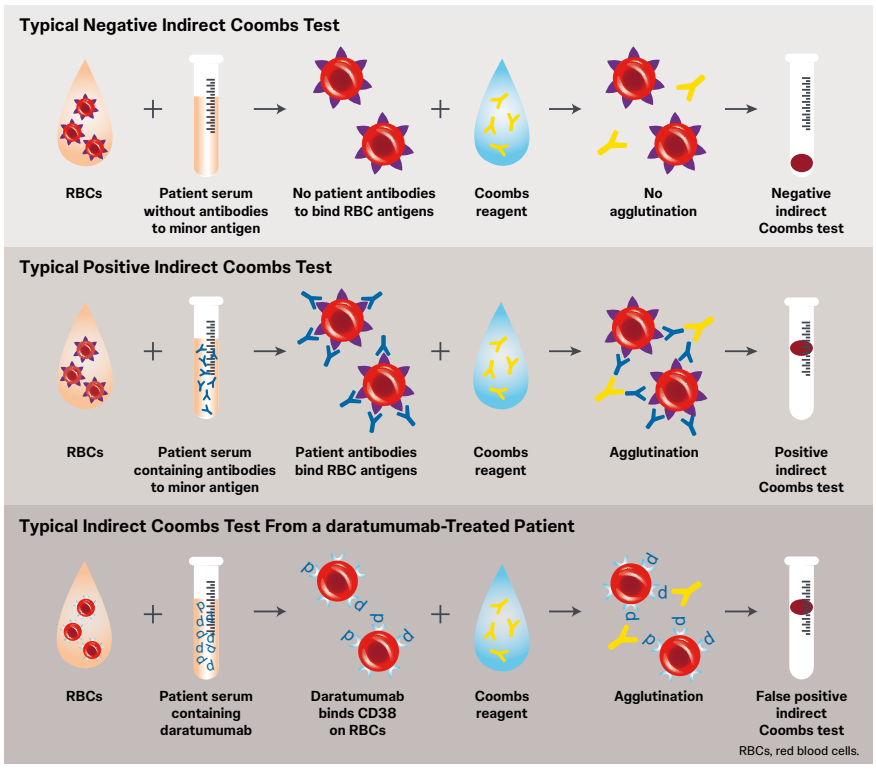
To Ensure Timely Transfusions

REMEMBER

If a patient who received daratumumab requires a transfusion:

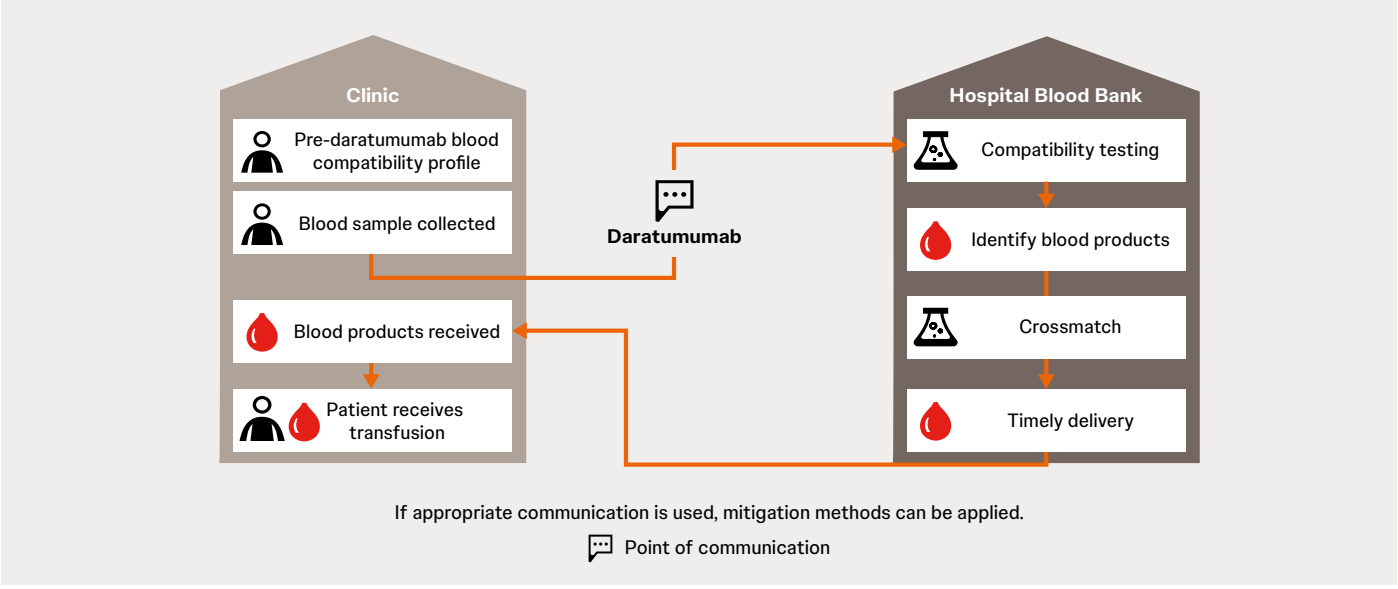
- Type and screen patients prior to starting daratumumab and inform the blood bank that your patient has been treated with daratumumab
- Ensure that your patient's blood sample is identified as containing daratumumab
- Double-check standing orders for transfusions to determine if your patient received daratumumab within the last year
- 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 and inform patients about the blood compatibility testing issue

Daratumumab Results in a False Positive Indirect Coombs Test



- Daratumumab is a human monoclonal antibody for the treatment of multiple myeloma, AL Amyloidosis, or smouldering multiple myeloma[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. Blood banks have been informed of this issue.

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.
- Failure to identify compatible donor units could lead to incompatible donor match.
- The interference mitigation methods include treating reagent RBCs with dithiothreitol (DTT) to disrupt daratumumab binding or other locally validated methods. Since the Kell Blood group system is also sensitive to DTT treatment, Kell-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs. Genotyping may also be considered.[7]
- **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 with cross-matching of blood 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.[1]
- Daratumumab does not interfere with identification of ABO/RhD antigens.[2]
- In the event of a planned transfusion, the healthcare professional should notify blood transfusion centres about the interference with indirect antiglobulin tests.
- 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 resulting in interference with cross matching of blood 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, please advise patients that they should carry their Patient Alert Card for 6 months after the treatment has ended.
- Patients should be provided with the Patient Alert Card and advised to consult the Patient Information Leaflet (PIL) for further information.

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.jnj.com/innovativemedicine/ireland/contact-us

Reporting of Adverse Events

Reporting suspected adverse events after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. 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, a Johnson and Johnson Company, on +44 1494 567447 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.