DARZALEX® (daratumumab) Card for Haematology/Transfusion Laboratory

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

This guide has been approved by the HPRA
EM-196585 | Date of approval: September 2026

Daratumumab Interference Mitigation Methods

REMEMBER

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

Daratumumab interference mitigation methods



OR



Treat reagent RBCs with DTT | *Genotype*

If available, refer to the Patient Alert Card for their blood type and antibody screen results conducted prior to initiation of daratumumab treatment.

DTT, dithiothreitol; RBCs, red blood cells.

Important risk minimisation information regarding interference with Blood Compatibility Testing:

Johnson&Johnson

References

1. Chapuy CI, Nicholson RT, Aguad MD, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55(6 Pt 2):1545–1554.
2. DARZALEX® Summary of Product Characteristics, available from www.medicines.ie.
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.
8. Westhoff CM, Reid ME. Review: the Kell, Duffy, and Kidd blood group systems. *Immunohematology*. 2004;20(1):37–49.

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.[2]
- 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.[6]
- 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 compatibility profile should be recorded on the Patient Alert Card.
- The healthcare professionals should provide a Patient Alert Card to their patients and advise them to consult the package leaflet.
- The patient should be advised to carry the Patient Alert 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.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.

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

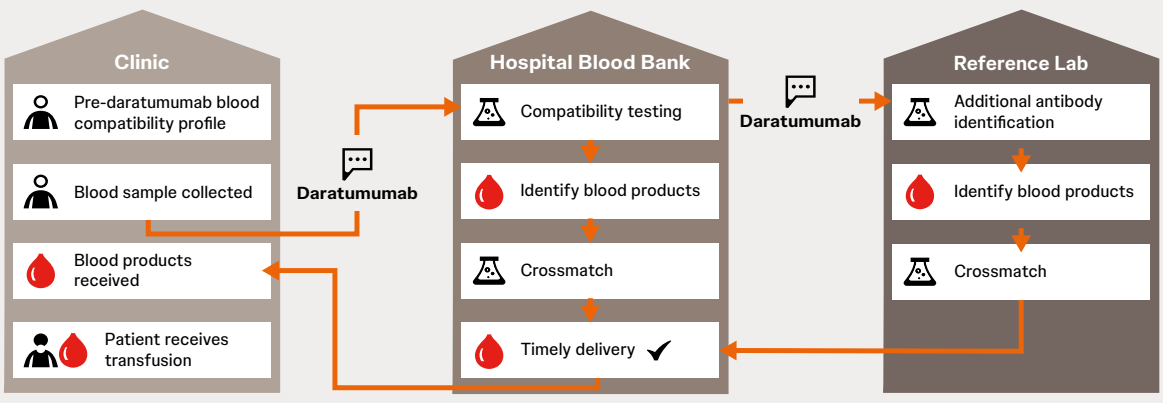
Typical Indirect Antiglobulin Test From a daratumumab-Treated Patient



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

- Daratumumab is a human monoclonal antibody for the treatment of multiple myeloma, AL amyloidosis, or smouldering multiple myeloma[2]
- 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 in the patient's serum. This interferes with compatibility tests, including the antibody screening and crossmatching[1]

Help Prevent Delays by Applying Mitigation Methods

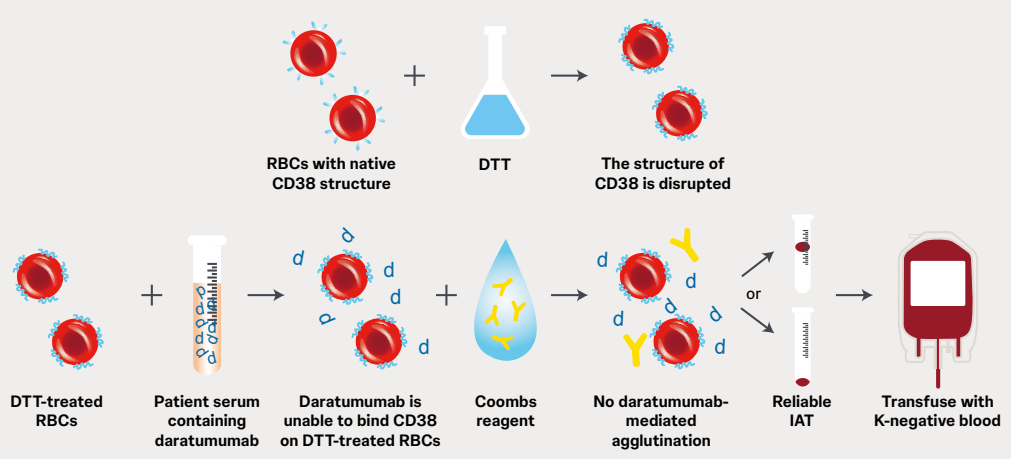


Use of daratumumab by the patient needs to be appropriately communicated for mitigation methods to be applied

Point of communication

- 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 genotyping[7]
- 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,[8] K-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs. Alternatively, genotyping may also be considered