October 2025
CP-557620

DARATUMUMAB

Understanding Daratumumab Interference with Blood Compatibility Testing

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.

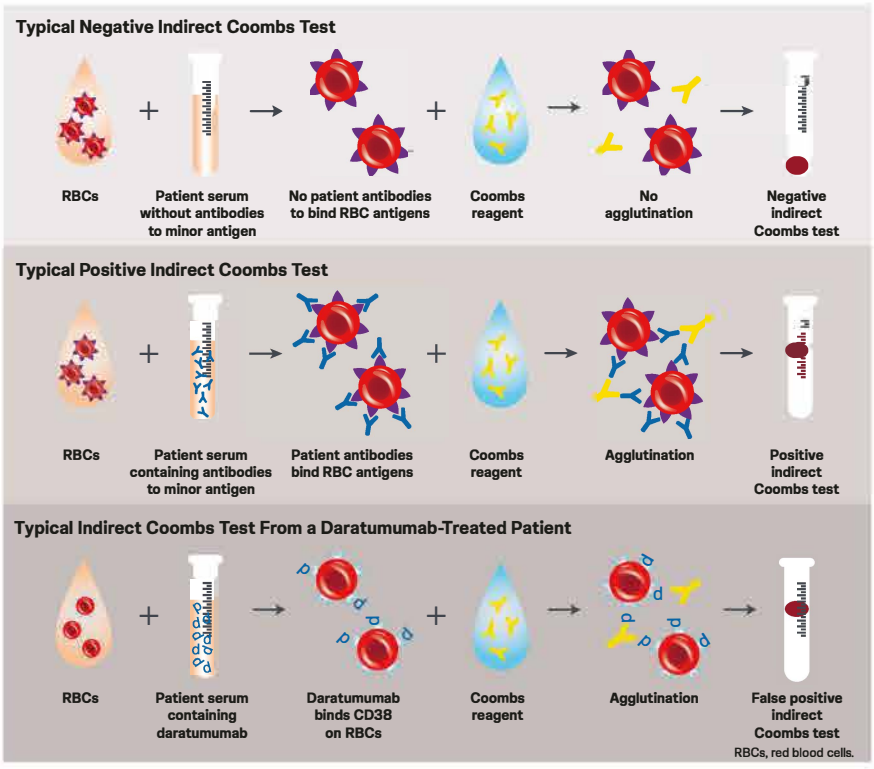
To Ensure Timely Transfusions

REMEMBER

If a patient who received daratumumab requires a transfusion:

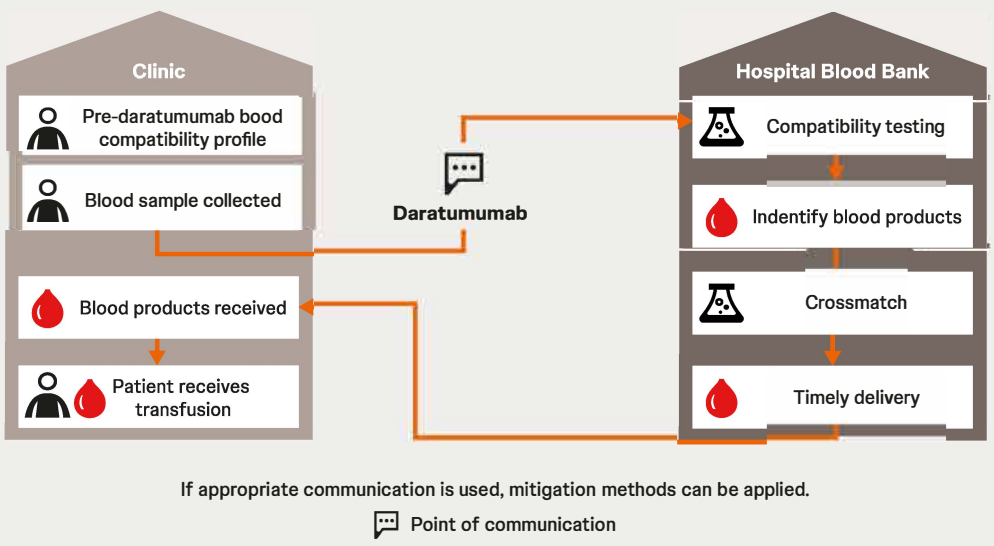
- Type and screen patients prior to starting daratumumab. Inform the blood bank that your patient has been treated with daratumumab which interferes with indirect antiglobulin tests
- Ensure that your patient's blood sample is identified as containing daratumumab
- Double-check standing orders for transfusions 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

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[1]
- 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[1]. 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 Janssen Medical Information by using one of the following methods:

Janssen PV department

Email: JACEG-PV@its.jnj.com

mobile :+20100629760

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.

في حالات الطوارئ، أو إذا وجدت هذه البطاقة،
يرجى الاتصال بالطبيب المذكور أدناه:

اسم/عيادة الطبيب، اسم المركز/المستشفى:

رقم الهاتف:

توجد

معلومات طبية هامة

ضمنه

للمرضى اللذين يعالجون باستخدام دواء داراتومومواب:

يرجى إبراز هذه البطاقة لمقدمي خدمات الرعاية الصحية قبل أي عملية نقل دم وحملها لمدة 6 أشهر من تاريخ نهاية العلاج

لمزيد من المعلومات، يرجى الرجوع لنشرة بيانات المريض

بطاقة تعريفية للمرضى اللذين يعالجون باستخدام داراتومومواب

الاسم: ----------

أنا أعالج باستخدام الأدوية الآتية: دواء داراتومومواب (أجسام مضادة)

لعلاج

السرطان النقوي (خلايا البلازما) المتعدد اوأميلويدوز السلاسل الخفيف

وقد توقفت عن تناول هذا الدواء في يوم ----- /شهر----- / سنة -----

السادة مقدمي خدمات الرعاية الطبية،

Daratumumab is associated with the risk of interference with blood typing. The Indirect Coombs test (Indirect antiglobulin test [IAT]) may show positive results in patients taking daratumumab, even in the absence of antibodies to minor blood antigens in the patient's serum which may persist for up to 6 months after the last dose. The determination of a patient's ABO and Rh blood type are not impacted.

If an emergency transfusion is required, non-cross-matched, ABO/RHD-compatible RBCs can be given per local blood bank practices.

For more information, please use this reference as a source of additional information: http://onlinelibrary.wiley.com/doi/10.1111/trf.13069/epdf
Or contact local medical information service at Janssen Egypt Scientific Office

Janssen PV department
***Mobile** :+20100629760*
***Email:** JACEG-PV@its.jnj.com*

قبل بدء العلاج باستخدام داراتومومواب، كانت نتائج تحليل الدم خاصتي،

التي أجريتها بتاريخ: يوم-----/شهر-----/سنة----- **كالآتي:**

فصيلة الدم: ☐ A ☐ B ☐ AB ☐ O ☐ Rh+ ☐ Rh−

Indirect Coombs test (antibody screen) was:

نتيجة تحليل كومبس غير المباشر (للأجسام المضادة) كانت:

☐ **Negative** سلبية ☐ **Positive** إيجابية (للأجسام المضادة التالية)

أخرى: ----------

بينات الاتصال للمركز الذي أجريت فيه تحاليل الدم: ----------

In case of emergency, or if you find this card, please contact the doctor listed below:

Doctor's Name/Clinic, Center or Hospital Name:

_____

Telephone contact:

_____

DARATUMUMAB

Johnson&Johnson

IMPORTANT MEDICAL INFORMATION INSIDE

Daratumumab PATIENTS: Provide this card to healthcare providers BEFORE blood transfusion and carry it for 6 months after treatment has ended. For further information please refer to the Patient Information Leaflet

Patient ID Card for Daratumumab

Name: _____

I am taking the following medication:
Daratumumab antibody product for the treatment of multiple myeloma or AL Amyloidosis

I stopped taking this medication on ___ /___ /___
DD MM YYYY

Dear Healthcare Provider,

Daratumumab is associated with the risk of interference with blood typing. The Indirect Coombs test (Indirect antiglobulin test [IAT]) may show positive results in patients taking daratumumab, even in the absence of antibodies to minor blood antigens in the patient's serum which may persist for up to 6 months after the last dose. The determination of a patient's ABO and Rh blood type are not impacted.

If an emergency transfusion is required, non-cross-matched, ABO/RHD-compatible RBCs can be given per local blood bank practices.

*For more information, please contact local safety team at Janssen PV department (Email: JACEG-PV@its.jnj.com or mobile :+201006297**60**) or use this reference as a source of additional information:* ***http://onlinelibrary.wiley.com/doi/10.1111/trf.13069/epdf***

Before starting daratumumab my blood test results collected on ___ /___ / ___ **were:**

DD MM YYYY

Blood type: ☐ A ☐ B ☐ AB ☐ O ☐ Rh+ ☐ Rh-

Indirect Coombs test (antibody screen) was:

☐ Negative ☐ Positive for the following antibodies:

_____

Other: _____

Contact details of institution where the blood tests were performed:

_____

Date of preparation: **October** 2025 CP-550565

CP - 557622