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.

To Ensure Timely Transfusions

References

daratumumab Results in a False Positive Indirect Coombs Test

- daratumumab is a human monoclonal antibody for the treatment of multiple myeloma.
- daratumumab binds to CD38, a protein that is expressed at low levels on red blood cells (RBCs).
- 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 (both indirect Coombs tests) that are part of a routine pretransfusion workup.

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 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.
- If an emergency transfusion is required, non-crossmatched, ABO/RhD-compatible RBCs can be given, per local blood bank practices.
- 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. 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.
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March 2021
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March 2021
To date, no clinically significant hemolysis has been observed in patients receiving daratumumab, and no transfusion reactions have occurred in patients requiring transfusions. However, as daratumumab interferes with red cell surface expression of CD38, it may be suggested that non-crossmatched, ABO/RhD-compatible RBCs are given, per local blood bank practices. A patient’s compatibility profile, determined prior to their first dose of daratumumab, is recorded on the patient’s ID card. A patient’s compatibility profile, determined prior to their first dose of daratumumab, is recorded on the patient’s ID card.

**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 transfusions (data on file).

**Daratumumab Interference Mitigation Methods**

- **Genotype**
  - Treat reagent RBCs with DTT or locally validated methods.

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**References**

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

- Daratumumab is a human monoclonal antibody for the treatment of multiple myeloma.
- Daratumumab binds to CD38, a protein that is expressed at low levels on red blood cells (RBCs).
- Daratumumab binding to RBCs may mask the detection of antibodies to minor antigens. This interferes with compatibility tests, including the antibody screening and crossmatching.

Help Prevent Delays by Applying Mitigation Methods

- 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 or by using genotyping.
- Mitigation methods should be used until pan-agglutination is no longer observed.

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Contact information:

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Fax: +966 11 2057662
Online: http://ade.sfda.gov.sa

For full prescribing information, please refer to the data sheet or contact Johnson & Johnson Middle East
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