Direct Healthcare Professional Communication

"Daratumumab Interaction with Blood Compatibility Testing- Information for Blood Transfusion Management Departments (Blood Banks)"

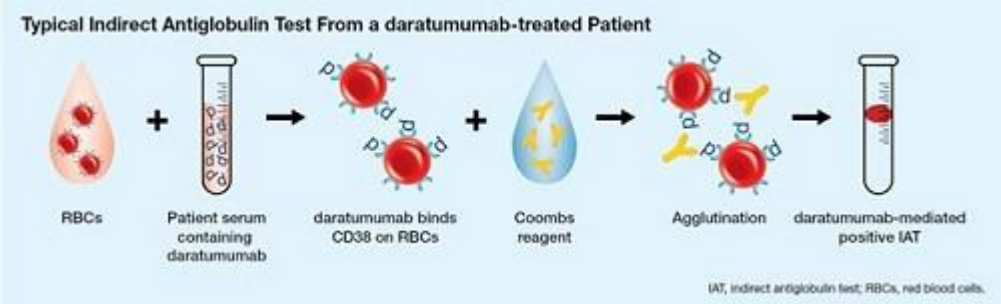
Dear Healthcare professional,

Janssen in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

- Daratumumab is a human monoclonal antibody for the treatment of 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 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.
- In case of urgent need for transfusion, non-cross matched ABO/RhD compatible RBC units can be administered as per local bank practices;
- Daratumumab-mediated positive indirect Coombs test (interfering with cross-matching of blood) may persist for up to 6 months after the last product's infusion,
- Therefore, the HCP should advise the patient to carry the Patient Alert Card until 6 months after the treatment has ended

Figure 1.

DARA Results in a Positive Indirect Antiglobulin test which may persist for up to 6 months after the last product's infusion



References

1- de Weers M, Tai YT, van der Veer MS, et al. Daratumumab, a novel therapeutic human CD38 monoclonal antibody, induces killing of multiple myeloma and other hematological tumors. *J fmmunol*. 2011;186(3):1840-1848.

2- Chapuy CI, Nicholson RT, Aguad MD, et al.. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55(6Pt 2):1545-15

For full information please refer to **QR code** linking you to Egyptian drug Authority (EDA) website

QR Code ⇨

Guidance on Adverse events Reporting

Egyptian Pharmaceutical Vigilance Center (EPVC) - Egyptian Drug Authority (EDA)

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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/RHDcompatible 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

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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: ----------