

Direct Healthcare Professional Communication 31 October 2022

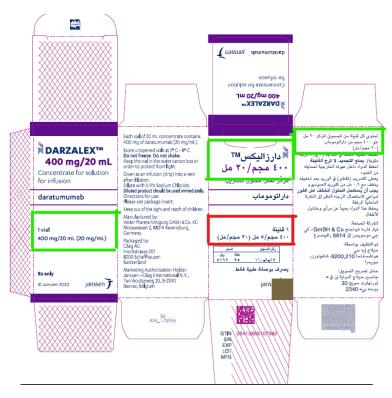
DARZALEX[®] (daratumumab) 400 mg/20 mL solution in a single-dose vial: Incorrect information about solution concentration in Arabic section of the outer pack.

Dear Healthcare Professional,

Johnson & Johnson Middle East Branch in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you about incorrect information on solution concentration stated in the Arabic section of the outer pack:

Summary

- Certain batches (LDS3E09, LDS3E14, LIS3213, LIS3507, LJS2A08, MAS4V05 & MBS2H05) of DARZALEX[®] (daratumumab) 400 mg/20 mL solution in a single-dose vial are showing incorrect information about solution concentration stated in the Arabic section of the outer carton box, indicating 400mg/5ml instead of 400mg/20ml.
- This error is presented only in the Arabic section of the outer carton box, However, the concentration in the English section is reflected correctly (400 mg/20 ml). In addition, please note that the self-adhesive inner label on the vial and the product's Patient Information Leaflet (PIL) reflect the correct information.
- The error is highlighted in red box below and the green boxes illustrate the correct translation.





• Please use the correct concentration information, 400mg/20ml when preparing the injection for a given patient.

As directed by SFDA, HCPs should mask the wrong concentration in Arabic part of the carton box.

In addition, the manufacturer will use permanent adhesive label with corrected information for any remaining quantities available in their stock.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Call for Reporting

Healthcare professional should report suspected adverse Events associated with this product in accordance with the national spontaneous reporting system:

SFDA (National Pharmacovigilance Center) Email: <u>npc.drug@sfda.gov.sa</u> Telephone: 19999 Fax: +966 11 2057662 Online: <u>http://ade.sfda.gov.sa</u>

Company Contact Points:

If you have further question or require additional information, please contact our local safety department at:

Email: <u>GCC-PV2@its.jnj.com</u> Tel: +966 11 4339133

Yours Faithfully,

Bulent Ozturk, MD

Medical Affairs Director – GCC Countries