

- 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: npc.drug@sfda.gov.sa

Telephone: 19999

Fax: +966 11 2057662

Online: <http://ade.sfda.gov.sa>

Company Contact Points:

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

Email: GCC-PV2@its.jnj.com

Tel: +966 11 4339133

Yours Faithfully,

Bulent Ozturk, MD

Medical Affairs Director – GCC Countries