March 11, 2020

Update on instruction for the preparation of Curam® (Amoxicillin Clavulanic Acid POS "powder for Oral Suspension") bottles:

Dear Healthcare Professional,

In agreement with Saudi Food and Drug Authority (SFDA), Sandoz, a Novartis Division, is committed to protect Patient Safety and strive towards keeping high national and international quality requirements in our operations.

Background:

- Following a recall conducted in May 2019 concerning Amoxicillin Clavulanic Acid POS complaints for lumps of powder, several improvements and Corrective and Preventive Actions (CAPAs) have been implemented:
- The incidence of unsealed bottles/ incorrectly sealed bottles has been substantially reduced.
- A residual risk of a minimal number of bottles to be incorrectly sealed remains statistically.
- In order to mitigate this risk, we would therefore like to inform you that we are in the process of updating Patient Information Leaflets (PIL) to reflect new instruction detail for the preparation of POS bottles as described in the attachments to this letter.

Please note that the process of updating the product artworks is ongoing, in full alignment with the Saudi Food and Drug Authority (SFDA) as required, and will be completed as soon as possible.

Please make sure to reconstitute the product in line with the attached instructions and provide the patient with the supportive instruction attached until the update of the PILs is completed.

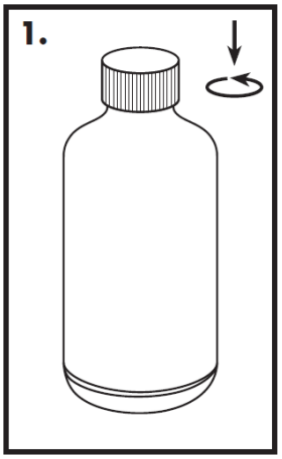
Kindly contact the undersigned, should you require further clarification or to report any suspected adverse reactions associated with the use of this product:

Novartis Consulting AG, Patient Safety Department:
Phone: +996112658100
Toll free number: 8001240078
Mobile: 0545544426 or 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com
Website: www.report.novartis.com

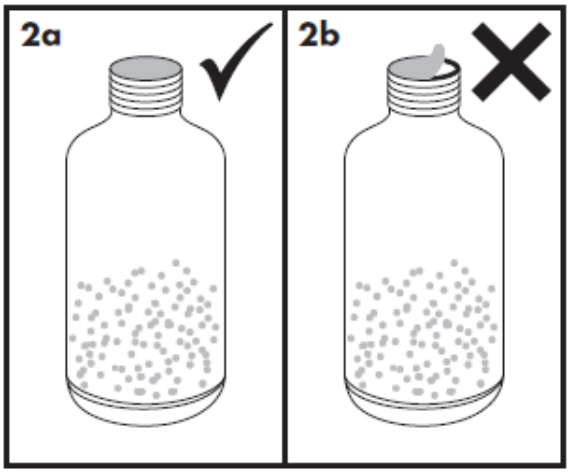
National Pharmacovigilance Center (SFDA):
Unified Contact Center: 19999
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Sincerely,

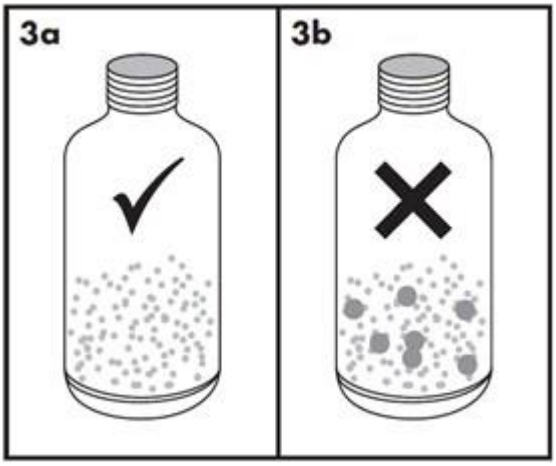
Malak Alowais
Patient Safety Manager (QPPV)
Novartis Saudi Arabia



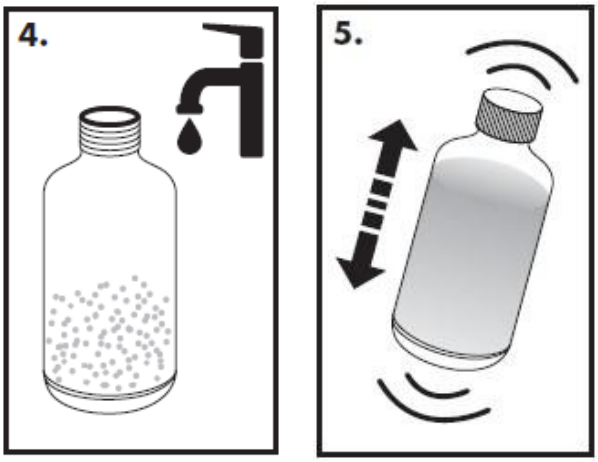
Remove the bottle cap by pressing down and rotating the bottle cap anti-clockwise



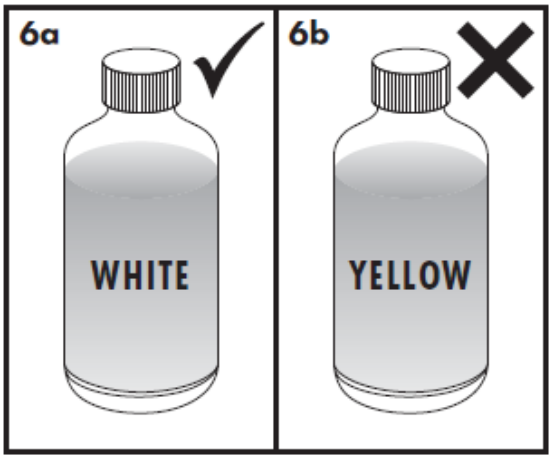
Check that the sealing membrane on the bottle mouth is intact



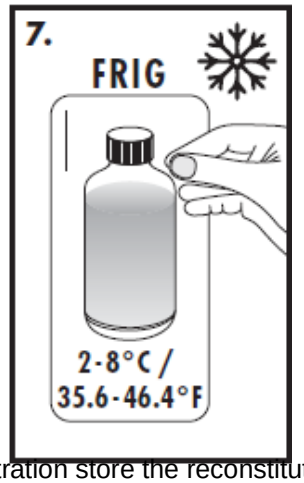
Check that no lumps are present inside the bottle



Remove the sealing membrane and reconstitute the product with drinking water according to the product information leaflet. Shake well, until a homogenous suspension is obtained.



Check that the color of the reconstituted solution is offwhite



After administration store the reconstituted suspension in the fridge