octapharma

Date: 4/8/2025

Human Fibrinogen, Fibryga Important Information Regarding Arabic Leaflet Printing Error

Dear Healthcare professional,
Octapharma would like to inform you of the following:
Octapharma in agreement with the Saudi Food and drug Authority (SFDA) would like to inform you about a printing error identified in the Arabic version of the Patient Information Leaflet (PIL) inserted within the carton of Fibryga (Human Fibrinogen Concentrate, 1 g, Powder for solution for injection or infusion), which classified as hospital item intended for inpatient usage. This letter is approved by Saudi Food and Drug Authority (SFDA).

Summary:

- The Arabic Patient Information Leaflet (PIL) included in Fibryga cartons contains a printing error related to the Preparation and Administration instructions.

- Healthcare professionals are advised to follow the correct instructions in the English version of the PIL.

- The printing error is limited to the Arabic version of the PIL and has no effect on the product's composition or quality.

Description of the Issue:

Arabic Patient Information Leaflet
Section: Instructions for Preparation and Administration
Reconstitution
1. Error:
Warm both the powder (Fibryga) and the diluent in unopened containers to room temperature. This temperature must be maintained during reconstitution. If a water bath is used for warming, care must be taken to avoid water contact with the rubber stoppers or container closures.
The water bath temperature must not exceed **+73°C (89°F).**
Correct:
Warm both the powder (Fibryga) and the diluent in unopened containers to room temperature. This temperature must be maintained during reconstitution. If a water bath is used for warming, care must be taken to avoid water contact with the rubber stoppers or container closures.
The water bath temperature must not exceed **+37°C (98°F).**
7. Error:
The dissolution of the powder should not take more than **03 minutes**. If the powder is not dissolved within **03 minutes**, the product must be discarded.

Correct:
The dissolution of the powder should not take more than **30 minutes**. If the powder is not dissolved within **30 minutes**, the product must be discarded.

الخلل	الصواب
النشرة الداخلية الخاصة بالمريض باللغة العربية **قسم**: تعليمات الاعداد والإعطاء **إعادة الاستنشاء** 1- قم بتدفئة كل من المسحوق (فايبريجا) والمذيب في حاويات غير مفتوحة بما يصل إلى درجة حرارة الغرفة. يجب الحفاظ على درجة الحرارة هذه أثناء إعادة الاستنشاء. إذا تم استخدام حمام مائي للاحترار فيجب توخي الحذر لتجنب ملامسة الماء للسدادات المطاطية أو أغطية الحاويات. يجب ألا تزيد درجة حرارة الحمام المائي عن **+ 73 درجة مئوية (89 درجة فهرنهايت)**	**النشرة الداخلية الخاصة بالمريض باللغة العربية** **قسم**: تعليمات الاعداد والإعطاء **إعادة الاستنشاء** **-1** قم بتدفئة كل من المسحوق (فايبريجا) والمذيب في حاويات غير مفتوحة بما يصل إلى درجة حرارة الغرفة. يجب الحفاظ على درجة الحرارة هذه أثناء إعادة الاستنشاء. إذا تم استخدام حمام مائي للاحترار فيجب توخي الحذر لتجنب ملامسة الماء للسدادات المطاطية أو أغطية الحاويات. يجب ألا تزيد درجة حرارة الحمام المائي عن **+ 37 درجة مئوية (98 درجة فهرنهايت)**
7- (لا ينبغي أن يستغرق حل المسحوق أكثر **من 03 دقيقة**. إذا لم يتم إذابة المسحوق خلال **03 دقيقة** فيجب التخلص من المنتج.)	7- (لا ينبغي أن يستغرق حل المسحوق أكثر **من 30 دقيقة**. إذا لم يتم إذابة المسحوق خلال **30 دقيقة** فيجب التخلص من المنتج.

Impact:
This printing error is limited to the Arabic version of the Leaflet, all product quality Attributes remain unchanged.

Recommendation:

- Please refer to the corrected (PIL) attached externally outside of the box of the product.
- Please refer to the correct instructions in the English leaflet at the same (PIL) inserted within carton.
- Distribute this information to all staff in the hospital involved in the preparation and administration of this product (Fibryga).

Corrective Actions:

- Corrected PIL attached externally to the box after SFDA approval.
- Updated Arabic leaflet is being prepared and will be included in the future shipments.
- The SFDA Quality Department has been notify of this issue.

Patients and healthcare professionals are encouraged to report any suspected adverse reactions to the Saudi Food and Drug Authority (SFDA) through the National Pharmacovigilance Center (NPC).

Scan the QR code below

or visit **https://ade.sfda.gov.sa** to report:

NPC Contact Details:
Email: npc.drug@sfda.gov.sa
Phone: 19999 (within Saudi Arabia)

You may also report adverse events to Octapharma.
For further pharmacovigilance inquiries or to report adverse events, please contact the Qualified Person for Pharmacovigilance (QPPV):
Email:
- Asma.al-dosari@octapharma.com
- Sa1-drugsafety@octapharma.com

Mobile:
+966561834663

Yours sincerely,

Asma Aldosari
QPPV