Danish Medicines Agency
Axel Heides Gade 1
2300 København S
Att.: Medicinsk Udstyr

FA-2022-040 22-Sep-2022

Subject: Field Safety Notice – Correction – Prismaflex Sets - Translation Error in Estonian IFU

Product Name: Prismaflex Sets

Dear Sir/Madam,

Baxter Healthcare Corporation is issuing a Correction for the Prismaflex sets listed in the FCA report.

This field action is related to the Prismaflex set Instructions for Use (IFU) and not the filter set itself.

The current Prismaflex set IFU is a single booklet containing 27 translated languages, and the following products include a mistranslation in the Estonian (Eesti) IFU. The mistranslation indicates contradictory information related to the patient body weight restrictions. If the Estonian IFU is being used, this could result in incorrect therapy settings or use of product for patients that are outside the intended population.

Baxter will be updating the IFU to correct the translation error.

The mistranslated IFU could result in use of the product for patients outside of the target population, which may lead to excessive therapy or blood loss in very low-weight patients. User recognition of the erroneous IFU may lead to a delay in initiation of therapy as further clarification is sought. There have been no reports of serious injury related to this issue.

Customers who are referring to the Estonian IFU should follow the instructions in the Customer Communication.

Customers who are not referring to the Estonian IFU should continue to follow the IFU instructions in their official language.

Our records indicate that 8 customers have received this product in Denmark. For your information, please find attached the communication that is being sent to those customers.

Should you have any questions, please contact Baxter.

Should you have any questions, please contact me at Nordic_RA@baxter.com

Yours Sincerely,

Baxter A/S

Tinna Sørensen
Specialist, Regulatory Affairs

Enclosures
FA-2022-040 - FSCA Report
FA-2022-040 - Customer Letter including Customer Reply Form

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