



October 2014

## **FEIBA 500 U & 1000 U powder and solvent for solution for infusion**

### **New product name and introduction of new presentation**

### **Important information to avoid potential risk of medication error**

Dear Healthcare Professional,

Baxter would, in agreement with the Health Products Regulatory Authority (HPRA), like to inform you of the following:

#### **Summary**

- **The trade name for FEIBA 500 U has been changed to “FEIBA 25 U/ml”.**
- **The trade name for FEIBA 1000 U has been changed to “FEIBA 50 U/ml”.**
- **A new presentation of 2500 U is being introduced which has the same name as the 1000 U pack size: “FEIBA 50 U/ml”. The new presentation is diluted with 50 ml sterile Water for Injections and may offer a single vial dosing option for some patients.**
- **Following pack sizes are available:**
  - FEIBA 25 U/ml: 1 x 500 U/20 ml - colored blue**
  - FEIBA 50 U/ml: 1 x 1000 U/20 ml - colored green**  
**1 x 2500 U/50 ml – colored purple**
- **Due to the same strength displayed in the trade name a potential risk of medication error between the presentations 1000 U and 2500 U has been identified.**

#### **Further information on the safety concern and the recommendations**

The following measures are being implemented to minimize the potential risk of medication error:

The packaging for all presentations will display the total amount of either 500 U, 1000 U or 2500 U. In addition packaging will contain colours to help differentiate the 3 presentations (blue for 500 U, green for 1000 U and purple for 2500 U). Each presentation is accompanied by a solvent vial containing the appropriate amount of sterile Water for Injections (20 ml for 500 U, 20 ml for 1000 U and 50 ml for 2500 U). Please also find enclosed an artwork mock-up of the carton for each presentation.

#### **Further information**

FEIBA 25 U/ml and FEIBA 50 U/ml is a powder and solvent for solution for infusion indicated for:

- Treatment of bleeding in hemophilia A patients with inhibitors.
- Treatment of bleeding in hemophilia B patients with inhibitors, if no other specific treatment is available.
- Treatment of bleeding in non-hemophiliacs with acquired inhibitors to factor VIII.



- Prophylaxis of bleeding in hemophilia A patients with inhibitors who have experienced a significant bleed or are at high risk of significant bleeding.

### **Call for reporting**

Please continue to report any suspected adverse reactions to FEIBA 25 U/ml or FEIBA 50 U/ml, including any associated with medication errors to the HPRA, preferably through the online reporting option at [www.hpra.ie](http://www.hpra.ie), or alternatively via the downloadable or Yellow Card report forms.

Any suspected adverse reactions and/or medication errors observed during use of FEIBA 25 U/ml or FEIBA 50 U/ml may also be reported to Baxter on 00 44 1635 206360 or by email to [vigilanceuk@baxter.com](mailto:vigilanceuk@baxter.com).

Should you have any questions regarding this issue, please feel free to contact Baxter Surecall on 00 44 1635 206345.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Iain McNeil', is written over a horizontal line.

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