2 May 2021

Direct Healthcare Professional Communication (DHPC)

Subject: Important Safety Information Regarding the Intended Administration of RECOTHROM Thrombin Topical (Recombinant)

Dear Healthcare Professional,

Baxter Healthcare Corporation, in agreement with the Saudi Food and Drug Authority, is communicating important safety information regarding the intended administration of RECOTHROM, a topical thrombin indicated to aid hemostasis. As indicated in the product labeling, RECOTHROM should never be administered intravenously. Intravenous use of RECOTHROM can result in serious and life-threatening adverse health consequences.

Summary:

RECOTHROM Thrombin topical (Recombinant), is a topical thrombin indicated to aid hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age. RECOTHROM may be used in conjunction with an absorbable gelatin sponge, USP.

The luer lock transfer syringe included with the RECOTHROM product/kit is intended for transferring the reconstituted RECOTHROM solution per the Prescribing Information (PI). In August 2020, Baxter changed the packaging to adhere the “Do Not Inject” sticker directly onto the transfer syringe to help further mitigate the inadvertent intravenous use of RECOTHROM. Users are instructed within the PI to place the sticker on the transfer syringe as a visual reminder not to inject the product intravenously. Prior to this change, RECOTHROM product was distributed prior to the packaging change and included a “Do Not Inject” sticker adhered to the inside flap of the product container box rather than on the transfer syringe.

Safety:

Intravenous administration of RECOTHROM is contraindicated and may result in blood clotting requiring clinical intervention. Baxter issued a Safety Alert to customers in Saudi Arabia in December 2020 containing the above information.

Further Recommendations/Contact Information for Reporting:

Healthcare providers may continue to use the RECOTHROM provided in the kits while following the label PI to apply the product topically only.

Call for reporting If you become aware of an adverse event involving any product of Baxter Healthcare please report in accordance with the national requirements via the national spontaneous reporting system, to:

The National Pharmacovigilance Center (NPC)

Landline: 19999 Fax: +966112057662

Toll free phone: 8002490000

E-mail: npc.drug@sfda.gov.sa

Website: https//:ade.sfda.gov.sa

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Yours sincerely,