Recothrom

THROMBIN TOPICAL (RECOMBINANT)

RECONSTITUTION INSTRUCTIONS

RECOTHROM IS FOR TOPICAL USE ONLY – DO NOT INJECT.

BEFORE USING RECOTHROM, REMEMBER:
Right patient. Right drug. Right dose. Right time. Right route of administration.

RECOTHROM Thrombin topical (Recombinant) Indication

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.

Important Risk Information

CONTRAINDICATIONS

- Do not inject directly into the circulatory system.
- Do not use for the treatment of massive or brisk arterial bleeding.
- Do not administer to patients with a history of hypersensitivity to RECOTHROM or any components of RECOTHROM.
- Do not use in patients with known hypersensitivity to hamster proteins.

Please see additional Important Risk Information on the back cover and accompanying Full Prescribing Information.

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RECOTHROM IS FOR TOPICAL USE ONLY – DO NOT INJECT.

Recothrom

THROMBIN TOPICAL (RECOMBINANT)

5,000 Unit* Reconstitution Instructions

* Units used herein represent international units of potency determined using a reference standard that has been calibrated against the World Health Organization Second International Standard for Thrombin.

Remove the contents of the RECOTHROM Reconstitution Kit.

1

Remove flip-off cap from the top of the RECOTHROM vial. Attach the needle-free transfer device: Snap it into place on the vial by placing the vial flat on a surface and attaching the transfer device straight into the center of the vial stopper.

2

Attach the prefilled diluent syringe to the needle-free transfer device.

3

Inject the 5 mL of diluent from the syringe into the product vial. Keep the syringe plunger depressed.

NOTE: DO NOT reuse the diluent syringe for transfer of the reconstituted product. Remove and discard the diluent syringe.

4

Gently swirl and invert the product vial until the powder is completely dissolved. Avoid excessive agitation.

5

Remove pre-printed **"DO NOT INJECT"** label from the outside of the syringe package. Apply the label to the provided empty transfer syringe.

6

Attach transfer syringe to RECOTHROM vial and withdraw RECOTHROM solution.

RECOTHROM is now ready to be transferred to a labeled receptacle in a sterile field.

RECOTHROM IS FOR TOPICAL USE ONLY – DO NOT INJECT.

No RECOTHROM Kit components contain latex. Use aseptic technique when handling the vials and syringes.

< Scan to watch RECOTHROM 5,000 Unit reconstitution

Please see Indication and Detailed Important Risk Information on the reverse side.

RECOTHROM IS FOR TOPICAL USE ONLY – DO NOT INJECT.

Recothrom

THROMBIN TOPICAL (RECOMBINANT)

20,000 Unit* Reconstitution Instructions

* Units used herein represent international units of potency determined using a reference standard that has been calibrated against the World Health Organization Second International Standard for Thrombin.

Remove the contents of the RECOTHROM Reconstitution Kit.

1

Remove the flip-off cap from the top of the RECOTHROM vial and the diluent vial. Attach a needle-free transfer device (one each) to the RECOTHROM and diluent vials and snap them into place by placing the vial on a flat surface and attaching the transfer device straight into the center of the vial stopper.

2

Open the sterile, empty 20 mL syringe package and attach the 20 mL syringe to the needle-free transfer device on the diluent vial. Injection of air into the diluent vial may facilitate withdrawal of the diluent.

3

Draw up 20 mL of diluent from the vial into the syringe.

4

Remove the diluent-filled syringe from the diluent vial and attach it to the transfer device on the RECOTHROM vial.

Transfer the 20 mL of diluent from the syringe into the RECOTHROM vial; the vacuum in the vial facilitates transfer.

5

Leave the syringe attached and gently swirl and invert the RECOTHROM vial until the powder is completely dissolved. Avoid excessive agitation.

6

Remove pre-printed **"DO NOT INJECT"** label from the outside of the syringe package and apply it to the syringe.

7

Withdraw RECOTHROM solution.

RECOTHROM is now ready to be transferred to a labeled receptacle in a sterile field.

RECOTHROM IS FOR TOPICAL USE ONLY – DO NOT INJECT.

No RECOTHROM Kit components contain latex. Use aseptic technique when handling the vials and syringes.

Please see Indication and Detailed Important Risk Information on the reverse side.

Scan to watch RECOTHROM 20,000 Unit reconstitution >

RECOTHROM Thrombin topical (Recombinant) Indication

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.

Important Risk Information

CONTRAINDICATIONS

Do not inject directly into the circulatory system.

Do not use for the treatment of massive or brisk arterial bleeding.

Do not administer to patients with a history of hypersensitivity to RECOTHROM or any components of RECOTHROM.

Do not use in patients with known hypersensitivity to hamster proteins.

WARNINGS AND PRECAUTIONS

RECOTHROM may cause thrombosis if it enters the circulatory system. Apply topically. DO NOT INJECT.

Hypersensitivity reactions, including anaphylaxis, may occur. RECOTHROM is produced in a genetically modified Chinese Hamster Ovary (CHO) cell line and may contain hamster or snake proteins.

ADVERSE REACTIONS

Thromboembolic adverse reactions were reported in 6% of surgical patients treated with RECOTHROM in all completed clinical trials (N=644).

Antibody formation to RECOTHROM occurred in <1% of patients. None of the antibodies detected neutralized native human thrombin.

USE IN SPECIFIC POPULATIONS

There is no available data regarding RECOTHROM in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with RECOTHROM thrombin.

Pediatric Use: Safety and efficacy have not been established in neonates.

Lactation: There is no information regarding the presence of RECOTHROM in human milk, the effects on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RECOTHROM and any potential adverse effects on the breastfed child from RECOTHROM or from underlying maternal condition.

Geriatric Use: Of 644 patients in clinical studies of RECOTHROM, 36% (n=232/644) were ≥65 years old and 15% (n=95/644) were ≥75 years old. No differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ORDERING INFORMATION

DESCRIPTION	ORDER NUMBER	NDC
RECOTHROM 5,000 IU Vial	ADS201801	0338-0322-01
RECOTHROM 20,000 IU Vial	ADS201803	0338-0326-01
RECOTHROM 20,000 IU + Spray Kit	ADS201804	0338-0330-01
RECOTHROM Spray Applicator Kit	ADS201802	Not Applicable

For questions or ordering information, go to advancedsurgery.baxter.com or contact your local Baxter representative.

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US-AS29-230001 v1 March 2023

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