

INDICATIONS AND USAGE

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

- **For topical use only. DO NOT INJECT.**
- RECOTHROM may cause thrombosis if it enters the circulatory system.
- 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.
- Antibody formation to RECOTHROM occurred in <1% of patients. None of the antibodies detected neutralized native human thrombin.

USE IN SPECIFIC POPULATIONS

- Pregnancy Category C. RECOTHROM should be given to a pregnant woman only if clearly needed.
- Pediatric Use: Safety and efficacy have not been established in neonates.
- 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.

To report SUSPECTED ADVERSE REACTIONS, contact Mallinckrodt Hospital Products, Inc. at 1-800-778-7898 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Risk Information and accompanying Full Prescribing Information.

IMPORTANT RISK INFORMATION

pocket for PI

 **RECOTHROM®**
Thrombin topical
(Recombinant)



Reconstitution instructions

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טלפון ישיר לקבלת מידע:
אמיר דולב, מנהל חטיבת התרופות 050-3366165

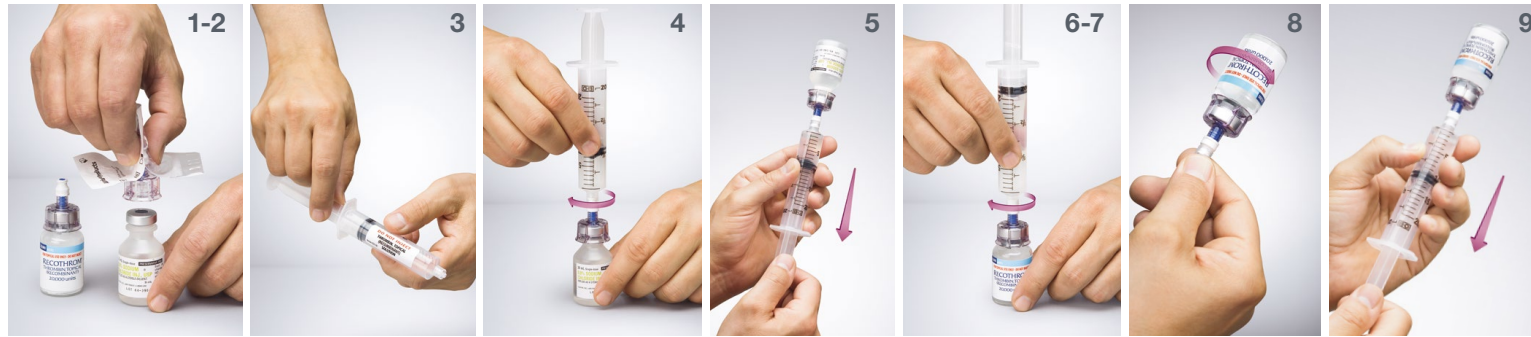
Reference: 1. RECOTHROM [package insert]. Parsippany, NJ: The Medicines Company; 2014.



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Mallinckrodt Hemostat Solutions

20,000-unit RECOTHROM Reconstitution Kit¹



1. Remove flip-off cap from the top of the RECOTHROM® Thrombin topical (Recombinant) vial and the diluent vial.
2. Attach one needle-free transfer device to the RECOTHROM vial and one to the diluent vial: Snap them into place on the vials by placing the vials flat on a surface and attaching the transfer devices straight into the **center** of the vial stoppers.
3. Open the sterile, empty 20 mL syringe package, and attach the preprinted “DO NOT INJECT” label to the syringe.
4. Attach the labeled 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).
5. Draw up 20 mL of diluent from the vial into the syringe.

(See step 6, next panel.)

Please see Important Risk Information inside and accompanying Full Prescribing Information.

6. Remove the diluent-filled syringe from the diluent vial, and attach it to the transfer device on the RECOTHROM vial.
7. Transfer the 20 mL of diluent from the syringe into the RECOTHROM vial; the vacuum in the vial facilitates transfer.
8. Leave the syringe attached. Gently swirl and invert the product vial until the powder is completely dissolved (avoid excessive agitation). The powder should dissolve in less than 1 minute at room temperature.
9. With the same syringe, draw up the RECOTHROM solution.

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

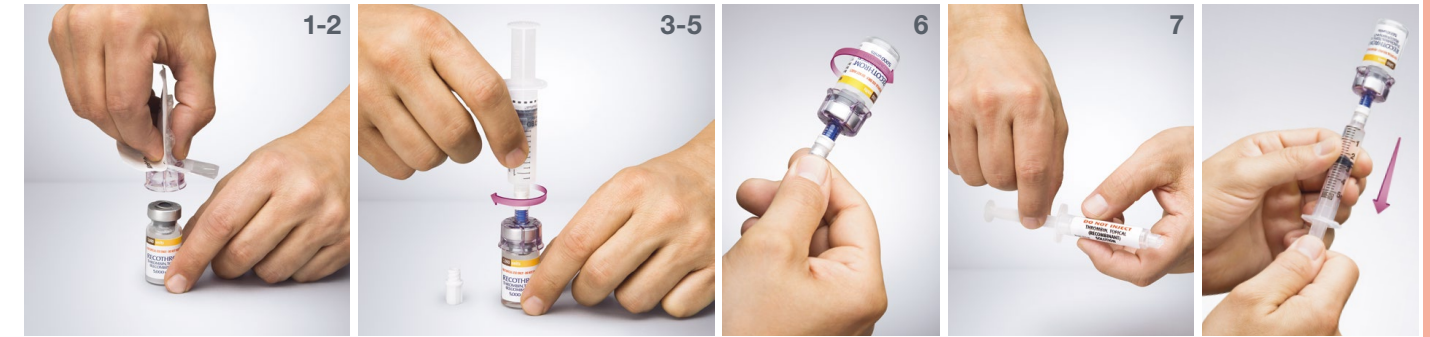
For topical use only. DO NOT INJECT.

No RECOTHROM Kit components contain latex.

Use aseptic technique when handling the vials and syringes.

20,000-unit RECOTHROM Reconstitution Kit

5000-unit* RECOTHROM Reconstitution Kit¹



1. Remove flip-off cap from the top of the RECOTHROM vial.
2. 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.
3. Attach the pre-filled diluent syringe to the needle-free transfer device.
4. Inject the 5 mL of diluent from the syringe into the product vial. Keep the syringe plunger depressed.
5. **DO NOT reuse the diluent syringe for transfer of the reconstituted product. Remove and discard the diluent syringe.**

6. Gently swirl and invert the product vial until the powder is completely dissolved (avoid excessive agitation). The powder should dissolve in less than 1 minute at room temperature.
7. Apply the preprinted “DO NOT INJECT” label to the sterile, empty transfer syringe provided, and then draw up the RECOTHROM solution.

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

For topical use only. DO NOT INJECT.

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

* 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.

5000-unit* RECOTHROM Reconstitution Kit