BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

RECOTHROM® Thrombin, topical (Recombinant)

Rx Only

The following is a brief summary of the full prescribing information for RECOTHROM Thrombin, topical (Recombinant).

INDICATIONS AND USAGE

RECOTHROM Thrombin, topical (Recombinant), is indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques is ineffective or impractical.

RECOTHROM may be used in conjunction with an absorbable gelatin sponge, USP.

DOSAGE AND ADMINISTRATION

- **For topical use only. DO NOT INJECT.**
- Reconstitute RECOTHROM powder with the provided sterile 0.9% sodium chloride injection, USP, yielding a solution containing 1000 units/mL.*
- Topically apply RECOTHROM solution directly to bleeding site or in conjunction with absorbable gelatin sponge. The amount required depends upon the area of tissue to be treated.

DOSAGE FORMS AND STRENGTHS

5000- and 20,000-unit vials of sterile powder for solution.

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 known hypersensitivity to RECOTHROM, any components of RECOTHROM, or hamster proteins.

WARNINGS AND PRECAUTIONS

- **Potential risk of thrombosis if absorbed systemically.**
- In patients with known hypersensitivity to snake proteins, there may be a potential for allergic reaction.

ADVERSE REACTIONS

- No specific adverse events have been established as adverse reactions causally related to RECOTHROM administration. In a Phase 3 clinical study comparing RECOTHROM to bovine thrombin,[1] adverse events were reported with similar frequency in the two treatment groups, and the most common events reported were incision site complication, procedural pain, and nausea.
- Treatment with RECOTHROM resulted in a statistically significantly lower incidence of specific anti-product antibody development. Three of 198 (1.5%; 95% CI, 0 to 4%) of the patients in the RECOTHROM arm developed specific anti-thrombin product antibodies (1 patient also developed anti-CHO host cell protein antibodies). Forty-three of 200 subjects (22%; 95% CI, 16 to 28%) in the bovine thrombin arm developed specific antibodies to bovine thrombin product. None of the antibodies in the RECOTHROM group neutralized native human thrombin. Antibodies against bovine thrombin product were not tested for neutralization of native human thrombin. Development of antibodies in **either** group did not lead to any adverse events such as excessive bleeding.
- Limited data (n=6) are currently available on repeat exposure to RECOTHROM.

To report SUSPECTED ADVERSE REACTIONS, contact ZymoGenetics, Inc. at 1-888-784-7662, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Pediatric use has not been evaluated in clinical studies.
- Geriatric: No substantive differences in safety or effectiveness were observed between patients 65 years of age or older and younger patients.

REFERENCES

[1] Chapman WC, Singla N, Genyk Y, McNeil JW, Renkens Jr KL, Reynolds TC, Murphy A, Weaver FA. A Phase 3, Randomized, Double-Blind Comparative Study of the Efficacy and Safety of Topical Recombinant Human Thrombin and Bovine Thrombin in Surgical Hemostasis. J Am Coll Surg 2007;205:256–265.

For Full Prescribing Information, access www.RECOTHROM.com

Manufactured for ZymoGenetics, Inc.

*Units used herein represent International Units of potency.

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