RECOTHROM® Thrombin

RECOTHROM is human thrombin that is produced via recombinant DNA technology from a genetically modified CHO cell line; it is not derived from animal or human blood. RECOTHROM 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 (such as suture, ligature, or cautery) is ineffective or impractical. It may be topically applied directly to the bleeding site or in conjunction with an absorbable gelatin sponge, USP.

It can be stored at room temperature and is convenient for lengthy surgeries; it is stable at room temperature up to 24 hours after reconstitution.

The following package configurations are available:

- 5,000 Unit RECOTHROM Kit (NDC 28400-105-41)
- 20,000 Unit RECOTHROM Kit (NDC 28400-120-41)
- 20,000 Unit RECOTHROM with Spray Device Kit (NDC 28400-120-50)

Important safety information includes:

- **RECOTHROM® Thrombin, topical (Recombinant) from ZymoGenetics is for topical use only and should not be injected directly into the circulatory system.**
- **RECOTHROM should not be used for the treatment of massive or brisk arterial bleeding** or in patients with known hypersensitivity to RECOTHROM, any components of RECOTHROM or hamster proteins.
- **There is a potential risk of blood clots if the product is absorbed into the circulatory system.**

In patients with known hypersensitivity to snake proteins, there may be a potential

for allergic reaction. The serious adverse event that occurred in ≥1% (n=6/583) of patients exposed to RECOTHROM in completed clinical trials was atrial fibrillation. The most common adverse events reported in these trials (N=583) were incision site pain (51%), procedural pain (30%), and nausea (28%). Adverse events reported in these trials were consistent with those commonly observed in surgical patients.

For more information including the Full Prescribing Information, please visit www.recothrom.com [1].

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[1] http://www.recothrom.com/