

# 5000-IU vial RECOBIN™-X

Thrombin, Topical (Recombinant)

A 5000-IU vial of RECOBIN-X powder, when reconstituted with 5 mL of sterile 0.9% sodium chloride, USP, from the supplied prefilled syringe yields a solution containing 1000 IU/mL of Thrombin, topical (Recombinant) for clinical use.

RECOBIN™ 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.

## 2 DOSAGE AND ADMINISTRATION

For topical use only. DO NOT INJECT.

Apply on the surface of bleeding tissue only.

The volume of reconstituted RECOBIN required will vary, depending on the size and number of bleeding sites to be treated and the method of application. The healthcare professional should determine the number of vials required to produce a sufficient volume of reconstituted product.

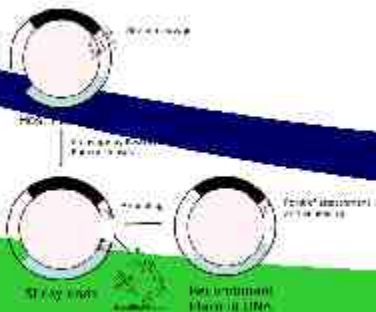
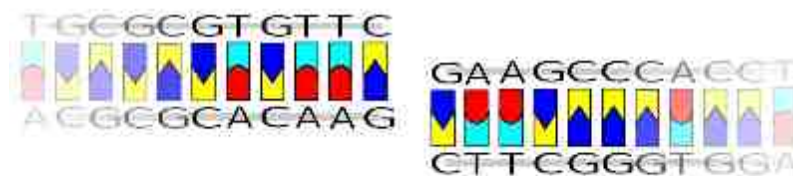
The following supplies are provided in each RECOBIN package:

- \* One vial of RECOBIN (5000 IU)
- \* One prefilled diluent syringe containing sterile 0.9% sodium chloride injection, USP (5 mL)
- \* One sterile, needle-free transfer device
- \* One sterile empty syringe (5 mL)

Inspect the integrity of the RECOBIN package and contents. Do not use if the packaging or contents have been damaged or opened.

### 2.1 Reconstitution of RECOBIN- X

The lyophilized powder is reconstituted, using the supplied diluent, in less than 1 minute at room temperature.



5000-IU vial  
**RECOBIN™-X**  
Thrombin, Topical (Recombinant)