



NATIONAL PBM ALERT

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DEPARTMENT OF VETERANS AFFAIRS-VETERANS HEALTH ADMINISTRATION (VHA) PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP), AND CENTER FOR MEDICATION SAFETY PSCI (VA MEDSAFE)

DANGER GIVING TOPICAL THROMBIN INTRAVASCULARLY-POTENTIAL FOR MEDICATION ERRORS

I. ISSUE

The Institute for Safe Medication Practices (ISMP) recently warned of the danger of accidental intravascular administration of topical thrombin. In several reported cases, patients accidentally injected with topical thrombin experienced adverse events ranging from an extended hospital stay to death.

II. BACKGROUND

Currently, there are three topical thrombin products available (Thrombin JMI®-bovine, Evithrom®-pooled human, Recothrom®-recombinant). All three products are clearly indicated for topical use only and NOT for injection. They are all FDA approved 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. They may also be used in conjunction with an absorbable gelatin sponge.

III. DISCUSSION

The ISMP is attempting to increase awareness of the danger of accidental intravascular injection of topical thrombin and to recommend steps to reduce this potentially serious medication error. In their February 2007 newsletter, ISMP presents three cases of unintentional or accidental intravascular injection of topical thrombin. One case resulted in a patient experiencing an apparent seizure, another required increased monitoring and an extended hospital stay and the final patient died.

ISMP points out that the confusion may arise partially because the packaging (vial and syringe) of some of the topical thrombin preparations have a similar appearance to parenteral products.

IV. VAMedSAFE RECOMMENDATIONS (Reinforce those of ISMP)

In an effort to reduce the risk of these types of medication errors, ISMP has recommended the following:

- Have the pharmacy prepare, label and dispense thrombin whenever possible, including dose used in the operating room.
- Healthcare workers may not be aware this product is for topical use only. As a result, receiving staff should be made aware of the adverse consequences of intravascular administration.
- Any syringe holding topical thrombin should be affixed with a label "For topical use only, do not inject."
- Never leave a vial or syringe containing topical thrombin at a patient's bedside because it may be confused as a parenteral product.
- During surgical procedures it may be possible to delay preparation and placement of topical thrombin in the surgical field until parenteral products have already been administered.
- Separate or sequester topical thrombin from parenteral products once drawn into the syringe and always communicate its presence when placing it in the surgical field.
- If appropriate for the type of surgery, consider using solutions of topical thrombin that can be used with an absorbable gelatin sponge. It may also be helpful to apply a dry form of topical thrombin on oozing surfaces
- Consider using spray kits, which are available for some of the topical thrombin products. The spray mechanism can help differentiate the topical thrombin from parenteral products. Never leave reconstituted topical thrombin in an unlabeled syringe before you attach the spray mechanism.

V. REFERENCES

1. <http://www.accessdata.fda.gov/psn/printer-full.cfm?id=109> (accessed 8-6-08)
2. http://www.ismp.org/Newsletters/acutecare/archives/NL_20070208.pdf (accessed 8-6-08)
3. http://www.ismp.org/newsletters/nursing/articles/2008_03-1.asp (accessed 8-6-08)