



Drug Class Review Monograph -- GPI Class 84 – Hemostatics

Review Time Frame: ~~January 2016~~ ~~February 02, 2016~~ ~~5~~ -- ~~01/January 2017~~ ~~6~~
Previous Class Review: N/A

Background:

Hemostatics are used as ~~an~~-adjuncts or alternatives to standard suturing techniques to control bleeding or for wound closure. Some of the systemic hemostatic agents include:

- Tranexamic aAcid – a synthetic derivative of the amino acid lysine that exerts its antifibrinolytic effect through the reversible blockade of lysine binding sites on plasminogen molecules.
- Aminocaproic aAcid -- binds to lysine-binding sites within the plasminogen/plasmin molecule.
- Phytonadione -- promotes the hepatic biosynthesis of vitamin K-dependent clotting factors.
- Desmopressin -- induces the release of von Willebrand factor from its storage sites in endothelial cells.

New ~~t~~Treatment guideline recommendations ~~pertain~~ing to hemostatics:

- None identified

Newly approved drugs:

- None identified

Newly approved formulations:

- None identified

Newly approved generics:

- None identified

Discontinued drugs:

- None identified

FDA Safety Alert/black box warnings:

- None identified

Pipeline alerts:

Agents pending FDA approval include:

- Andexanet alfa – antidote for the oral factor Xa (FXa) inhibitors – a Complete Response Letter was given for andexanet’s BLA. FDA requested Portola Pharmaceuticals to provide additional information primarily related to manufacturing as well as additional data to support inclusion in the label of two additional anticoagulants, edoxaban and enoxaparin.

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Summary/Recommendation:

***generic availability**

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1. Hoots WK, Shapiro AD. Treatment of hemophilia. Mahoney DH, Tirnauer JS. (Ed), UpToDate. Waltham MA. Accessed January 2016.

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3. US Script Oracle PBM: Medi-Span® Master Drug Data Base. January 2016.

4. Pharmacy & Therapeutics Management [database online]. Bay Harbor Islands, FL: IPD Analytics, LLD. Accessed February 2017. Available at: www.ipdanalytics.com.

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