

Drug Injury Watch: September 2016 Savaysa Label Change Points Out There Is Still No Antidote

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 27, 2016)

Savaysa (edoxaban) is a factor Xa inhibitor which was approved by the FDA in 2015. Savaysa has the following so-called “indications” or approved uses:

1. To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; and,
2. For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5–10 days of initial therapy with parenteral anticoagulant.

In relevant part, from a September 15, 2016 FDA letter to Daiichi-Sankyo, Inc.:

Prior Approval supplemental new drug application provides for changes to SAVAYSA prescribing information based on results of the Phase 1 trial DU176b-A-U158 that evaluated the effects of Prothrombin Complex Concentrate (PCCs) on reversing the pharmacologic activity of edoxaban tosylate. Sections 5.3 ‘Risk of Bleeding’ and 12.2 ‘Pharmacodynamics’ have been updated to include this information.

For some related news as regards the FDA and Savaysa, see this article, “[Xarelto / Savaysa / Eliquis: Antidote Drug AndexXa Is Rejected By FDA In August 2016](#)”, over at our Drug Injury Watch blog.

We will continue to monitor the safety profile of Savaysa as well as Eliquis and Xarelto, especially as regards the current lack of any FDA-approved antidote which would act as a reversal agent for serious bleeding events such as intracranial hemorrhages or hemorrhagic strokes and gastrointestinal (GI) bleeds.

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Earlier articles by attorney Tom Lamb on the [Side Effects Blog](#):

- [Antidote Drug For Xarelto / Savaysa / Eliquis Is Denied FDA Approval](#)
- [Doctors Are Concerned About Lack Of Savaysa Antidote To Stop Bleeding](#)
- [Possible Blood Level Testing For Eliquis / Xarelto / Pradaxa / Savaysa](#)
- [Eliquis, Savaysa, And Xarelto Worry Doctors Because No Antidote, Still](#)
- [Eliquis Might Be Safer Than Xarelto, But Neither Has Approved Antidote](#)

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers’ Comments.

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