

## Bevyxxa™ (betrixaban) – New drug approval

- On June 23, 2017, the [FDA announced](#) the [approval](#) of [Portola Pharmaceuticals' Bevyxxa \(betrixaban\)](#) for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.
  - The safety and effectiveness of Bevyxxa have not been established in patients with prosthetic heart valves because this population has not been studied.
- Bevyxxa is an oral factor Xa inhibitor that inhibits free factor Xa and prothrombinase activity, ultimately decreasing thrombin generation.
- The safety and efficacy of Bevyxxa were based on data from the APEX study of 7,513 patients hospitalized for an acute medical illness with VTE risk factors randomized to treatment with Bevyxxa for 35 to 42 days or treatment with enoxaparin for 6 to 14 days for VTE prophylaxis.
  - Efficacy was measured in 7,441 patients by a composite of either the occurrence of asymptomatic or symptomatic proximal deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE), or VTE-related death.
  - The primary outcome occurred in fewer patients receiving Bevyxxa (4.4%) vs. those taking enoxaparin (6%) [Relative risk (RR) = 0.75, 95% CI: 0.61, 0.91].
  - Fewer symptomatic events, defined as symptomatic DVT, non-fatal PE or VTE-related death, were observed with Bevyxxa vs. enoxaparin (0.9% vs. 1.5%, respectively; RR = 0.64, 95% CI: 0.42, 0.98).
- Bevyxxa carries a boxed warning for spinal/epidural hematoma.
- Bevyxxa is contraindicated in patients with active pathological bleeding and in patients with severe hypersensitivity reaction to betrixaban.
- Warnings and precautions of Bevyxxa include risk of bleeding, spinal/epidural anesthesia or puncture, use in patients with severe renal impairment, and use in patients on concomitant P-gp inhibitors.
- The most common adverse reaction (> 5%) with Bevyxxa use was bleeding.
- The recommended dose of Bevyxxa is an initial single dose of 160 mg, followed by 80 mg once daily, taken at the same time each day with food. The recommended duration of treatment is 35 to 42 days.
- Portola Pharmaceuticals' plans to launch Bevyxxa between August and November 2017 as 40 mg and 80 mg capsules.