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Mylan announces US launch of Bivalirudin for Injection

19 June 2018 | News

Mylan is offering Bivalirudin for Injection, 250 mg single-dose vial, to its hospital and institutional customers.

Global pharmaceutical company Mylan has announced the US launch of Bivalirudin for Injection, 250 mg single-dose vial, a generic version of Angiomax from The Medicines Company. The product is a direct thrombin inhibitor indicated for use as an anticoagulant in patients.

Mylan is offering Bivalirudin for Injection, 250 mg single-dose vial, to its hospital and institutional customers after an Abbreviated New Drug Application (ANDA) for the product was approved by the US Food and Drug Administration (FDA).

Bivalirudin for Injection is indicated for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA); undergoing percutaneous coronary intervention (PCI) with provisional use of glycoprotein IIb/IIIa inhibitor (GPI) as in the REPLACE-2 study; or with, or at risk of, heparin-induced thrombocytopenia (HIT) or heparin induced thrombocytopenia and thrombosis syndrome (HITTS), undergoing PCI.

It is intended for use in these indications with aspirin. The safety and effectiveness have not been established in patients with acute coronary syndromes who are not undergoing PTCA or PCI.