

FDA nod for Lupin's angina generic Ranolazine

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Mumbai: Lupin Pharmaceuticals has received final approval for its Ranolazine extended-release tablets, 500 mg and 1000 mg from the US FDA.

Lupin's Ranolazine extended-release tablets are the AB-rated generic equivalent of Gilead Sciences' Ranexa extended-release tablets, 500 mg and 1000 mg strengths. Ranolazine extended-release tablets are indicated for treatment of chronic angina.

Lupin believes that it is the first applicant to file an ANDA (abbreviated new drug application) for Ranexa extended-release tablets 500 mg and 1000 mg strengths and as such will be entitled to 180 days of marketing exclusivity.