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FDA approves generic versions of Plavix

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Singapore: The US Food and Drug Administration has approved generic versions of the blood thinning drug Plavix (clopidogrel bisulfate), which helps reduce the risk of heart attack and stroke by making it less likely that platelets in the blood will clump and form clots in the arteries. Clopidogrel is FDA-approved to treat patients who have had a recent heart attack or a recent stroke, or have partial or total blockage of an artery (peripheral artery disease).

A statement released by the FDA said Dr Reddy's Laboratories, Gate Pharmaceuticals, Mylan Pharmaceuticals, and Teva Pharmaceuticals have gained approval for 300 mg clopidogrel. Mylan and Teva also have approval for 75 mg clopidogrel along with Roxane Laboratories, Sun Pharma, Torrent Pharmaceuticals, Apotex and Aurobindo Pharma

"For people who must manage chronic health conditions, having effective and affordable treatment options is important," said Mr Keith Webber, deputy director of the Office of Pharmaceutical Science, FDA's Center for Drug Evaluation and Research. "The generic products approved today will expand those options for patients."

Clopidogrel has a boxed warning to alert healthcare professionals and patients that the drug may not work well for those with certain genetic factors that affect how the body metabolizes the drug. Patients can be tested for these genetic factors to ensure that clopidogrel is the right choice for them. Also, certain medicines, such as proton pump inhibitors Prilosec (omeprazole) and Nexium (esomeprazole), reduce the effect of clopidogrel, leaving a person at greater risk for heart attack and stroke.