

FDA says heartburn drugs can interfere with Plavix

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In this July 28, 2006 file photo, blood thinner medication Plavix is shown in New York. Federal health officials said Tuesday, Nov. 17, 2009, a popular heartburn medication can interfere with the blood thinner Plavix, a drug taken by millions of Americans to reduce risks of heart attack and stroke.(AP Photo/Mark Lennihan, File)

(AP) -- Federal health officials said Tuesday a popular variety of heartburn medications can interfere with the blood thinner Plavix, a drug taken by millions of Americans to reduce risks of heart attack and stroke.

The [Food and Drug Administration](#) said the stomach-soothing drugs Prilosec and Nexium cut in half the blood-thinning effect of [Plavix](#), known generically as [clopidogrel](#).

Regulators said the key ingredient in the heartburn medications blocks an enzyme the body needs to break down Plavix, muting the drug's full effect. Procter & Gamble's Prilosec is the over-the-counter version of AstraZeneca's Nexium, which was first approved in 2001.

"Patients at risk for heart attacks or strokes who use clopidogrel to prevent blood clots will not get the full effect of this medicine," the agency said in a statement.

Plavix is marketed by Sanofi-Aventis and Bristol-Myers Squibb. With global sales of \$8.6 billion last year, it's the world's second-best selling drug behind Pfizer's cholesterol drug Lipitor.

Because Plavix can upset the stomach, it is often prescribed with [stomach](#) acid-blocking drugs.

The FDA says patients who need to reduce their acid should take drugs from the H-2 blocker family, which include Johnson & Johnson's Mylanta and Boehringer Ingelheim's Zantac. FDA scientists say there is no evidence those drugs interfere with Plavix's blood clotting.

Nexium and Prilosec are part of a class of drugs known as proton pump inhibitors, but FDA regulators said they don't have enough information to say whether other drugs in that class shouldn't be used with Plavix.

"There's not enough data to tell us how those drugs interact with," the enzyme that activates Plavix, said Mary Ross Southworth, FDA's deputy director for safety of cardiovascular products. "There are ongoing studies looking at those other drugs."

The FDA said the warnings on Plavix have been strengthened based on a 150-patient study submitted by Sanofi over the summer.

Information about the drug interaction between Plavix and certain heartburn medications is not new. Researchers reported last year that taking Plavix with Nexium significantly increased patients' chances of being hospitalized for a [heart attack](#), [stroke](#) or chest pain.

In January, Sanofi and Bristol-Myers updated Plavix's labeling to advise against using it in combination with certain heartburn drugs.

A Sanofi spokeswoman said Tuesday that the company has bolstered that language labeling.

"We've strengthened the label to say that these drugs should be avoided altogether, not just discouraged," said Noelle Boyd, Sanofi's senior communications director.

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