FDA warning: some patients cannot process Plavix

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In this July 28, 2006 file photo, blood thinner medication Plavix is shown in New York. The Food and Drug Administration is adding its strongest warning to the label for Plavix Friday, March 12, 2010, after reports that some patients cannot process the blood thinning drug.(AP Photo/Mark Lennihan, file)

(AP) -- The Food and Drug Administration is adding its strongest warning to the label for Plavix, cautioning that some patients do not respond to the blockbuster blood thinner.

The FDA said in a statement Friday that certain patients with a genetic variation cannot metabolize the drug, putting them at increased risk for heart attack and stroke.

Patients can determine if they are "poor metabolizers" by taking a genetic test. The FDA recommends these patients use other blood thinners, such as aspirin.

The FDA added similar language to Plavix's label in November, but the new warning appears within a black box, the FDA's most severe safety labeling.

Plavix is prescribed to heart disease patients to prevent dangerous blood clots, which can cause heart attack, stroke and death.

With genetic tests costing around $500, experts say it's unlikely such testing will become standard for patients taking Plavix.

"I think based on this people will do more genetic testing, but I think it's premature to say that everyone who gets Plavix needs to be tested," said Dr. Louis Teichholz, head of cardiology at Hackensack University Medical Center.

Teichholz said the black box warning on Plavix could push more doctors to prescribe Effient, a competing blood thinner launched by Eli Lilly & Co. last summer.

In order to work effectively, Plavix must be broken down by a particular liver enzyme. But FDA says 2 to 14 percent of people in the U.S. have low levels of the enzyme, preventing them from successfully processing Plavix. The likelihood of being a non-responder varies by race, according to the FDA.

"Patients should not stop taking Plavix unless told to do so by their health care professional," the agency said in an online statement. "They should talk with their health care professional if they have any concerns about Plavix, or to find out if they should be tested for being a poor

metabolizer."

Using a higher dose of Plavix can increase blood thinning in non-responsive patients, according to the new label, though higher doses have not been cleared by the FDA.

Plavix is marketed by Sanofi-Aventis and Bristol-Myers Squibb. With global sales of $8.6 billion in 2008, it was the world's second-best selling drug behind Pfizer's cholesterol drug Lipitor.

A spokeswoman for New York-based Bristol-Myers said the company would add the new labeling to bottles of Plavix over the next two months.

"The revisions to the prescribing information for Plavix reflect the companies' ongoing research in collaboration with the FDA," said Laura Hortas.

In November, the FDA warned that taking stomach-soothing drugs like Prilosec and Nexium alongside Plavix could cut the blood-thinner's effect in half. Regulators said the key ingredient in the heartburn medications blocks the same liver enzyme needed to break down Plavix, muting the drug's full effect.

Shares of Bristol-Myers Squibb Co. fell 7 cents to $25.89. Shares of Sanofi-Aventis fell 30 cents to $37.89.