

Report: Bextra heart risks similar to Vioxx

Study shows arthritis drug has high incidence of attacks, stroke

REUTERS
JANUARY 10, 2004

NEW YORK - The arthritis drug Bextra, made by Pfizer Inc., has shown a high incidence of heart attacks and strokes among patients, according to an American Heart Association study, the New York Times reported on Wednesday.

Bextra is similar to Merck & Co.'s drug Vioxx. Merck voluntarily recalled Vioxx from shelves in late September when a study showed it increased the risk of a cardiac event.

The AHA's preliminary study of Bextra was unveiled on Monday at a meeting in New Orleans, which pooled data from 5,930 patients taking part in 12 trials. It found 2.19 times the number of heart attacks or strokes among patients given Bextra, compared with those given placebos, the Times reported.

"The magnitude of the signal with Bextra is even higher than what we saw in Vioxx. This is a time bomb waiting to go off," Dr. Garret A. FitzGerald, a cardiologist and pharmacologist at the University of Pennsylvania who presented the study, told the Times in an interview.

The newspaper said that the new study of Bextra was not considered to be as persuasive as the trial that led to Vioxx's withdrawal because it was backward-looking and reorganized data that had been presented in other settings.

A spokeswoman for Pfizer told the Times that heart problems with Bextra appeared only in studies involving patients at very high risk of heart disease who were undergoing cardiac surgery -- a detail Pfizer disclosed on Oct. 15.

Other studies of Bextra, involving 8,000 patients with arthritis who were followed for 6 to 52 weeks, found no heart problems, she told the newspaper.

A representative for Pfizer was not immediately available to comment to Reuters early on Wednesday.