FDA warns of heart risk with HIV drug combination

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(AP) -- The Food and Drug Administration issued a warning Tuesday about potential heart risks when combining two HIV drugs.

The agency said preliminary data suggest Roche's Invirase and Abbott Laboratories' Norvir can affect the electrical activity of the heart when used together. Changes to the heart's electrical activity can delay the signals that trigger heart beats.

In some cases the problem can cause irregular heart rhythms, leading to lightheadedness, fainting, and even death.

The FDA made its announcement after reviewing data submitted by Roche about the heart activity of patients using its drug with Abbott's Norvir. The agency said its review is ongoing and patients should not stop taking Invirase without talking to their doctor.

Doctors should review patients' heart health and current medications to determine if they should continue taking Invirase, the agency said in a statement posted online.

Invirase was approved in 1995 and is marketed by Genentech, the biotech unit of Swiss drugmaker Roche.

The drug is used in combination with Norvir and other anti-viral drugs to control HIV in adults. Norvir is given at a low dose to boost the level of Invirase in the body.

The FDA previously asked Roche and all makers of protease inhibitor drugs, which includes Invirase, to conduct studies of the heart side effects of their products.

A spokeswoman for Genentech said the company has submitted new drug labeling to Invirase which is under FDA review.

"The safety of patients is of the utmost importance to Genentech, and we continue to monitor and report to FDA adverse event reports from patients and physicians," Tara Cooper said in a statement.

A spokesman for Abbott, based in North Chicago, Ill., could not immediately provide comment.

HIV attacks the body's immune system, eventually causing AIDS. Just over 1.1 million Americans are estimated to have HIV and 232,000 do not know it, according to the Centers for Disease Control and Prevention.

The FDA issued Tuesday's warning under its so-called early communication program, which seeks to alert the public to a potential side effect with a drug immediately, even if no direct link has been established.