Norvir-Boosted Invirase Potentially Linked to Abnormal Heart Rhythms, FDA Warns

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The combination of Norvir (ritonavir)–boosted Invirase (saquinavir) may be associated with adverse effects on the heart, according to an announcement released today by the U.S. Food and Drug Administration (FDA).

Though the agency is still uncertain if there is a link between Norvir/Invirase and heart rhythm disturbances—its investigation of data provided by Invirase manufacturer Genentech, a division of Roche, is ongoing—its "early communication" is in keeping with the FDA's commitment to inform the public about ongoing safety reviews of drugs.

When used together, the FDA writes, the drugs may cause a condition called torsades de pointes, a type of abnormal heart rhythm. The abnormalities—which can be detected using an electrocardiogram—can also lead to interrupted electrical impulses to the heart muscle, technically referred to as heart block. Both conditions can lead to lightheadedness, fainting or abnormal heart beats. In some cases, torsades de pointes can progress to life-threatening irregular heart beat known as ventricular fibrillation.

The FDA is currently reviewing the data to make sense of the heart rhythm disturbances and to determine if there is definitely a link between the use of Norvir-boosted Invirase and electrocardiogram abnormalities. According to the agency, the risk might be increased only among those taking other medications known to cause heart rhythm abnormalities or in those with a history of abnormal echocardiograms.

The FDA suggests that people living with HIV using Norvir-boosted Invirase talk with their health care professional about any questions or concerns they have about Invirase. Similarly, the FDA is encouraging patients and health care providers to report any side effects from Invirase to the FDA's MedWatch program.