Norvir-Boosted Invirase May Cause Dangerous Heart Rhythms

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The combination of Norvir (ritonavir)–boosted Invirase (saquinavir) may be associated with a life-threatening side effect on the heart, according to new changes to Invirase's prescribing information announced by the FDA on Thursday, October 21, and reported by PR Newswire. The prescribing information changes follow a preliminary announcement in February describing a potential link between Norvir/Invirase and heart rhythm disturbances.

When used together, the revised prescribing information states, Abbott's Norvir and Genentech's Invirase 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.

In addition to the prescribing information changes, the FDA is requiring a medication guide for patients using Invirase that will describe these potential risks. Patients at greater risk of developing one of the serious heart events described above include those with underlying heart conditions or those with existing heart rate or rhythm problems.

"These heart conditions could potentially be life-threatening, and we want to assure that health care providers and patients are adequately informed of the risks," said Edward Cox, MD, MPH, director of the Office of Antimicrobial Products at the FDA's Center for Drug Evaluation and Research. "Patients should talk to their doctor if they have any concerns about their treatment. Certain drugs may interact with Invirase and increase the risk of developing these side effects, so patients should be sure to tell their doctor about other medicines they may be taking, including nonprescription medicines, vitamins and herbal supplements."

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