



The FDA Safety Information and Adverse Event Reporting Program

Saquinavir

[02/23/2010]

美國FDA 最近評估一臨床試驗資料，發現併用saquinavir(藥品名稱Invirase)及ritonavir(藥品名稱Norvir)二種抗病毒藥物治療人類免疫缺乏病毒(HIV)感染，可能會影響病人心臟電位，增加心律整之不良反應，包括延長QT 和PR interval。但這些不良反應是否確實因使用抗病毒藥品所導致，仍須進一步評估。

Saquinavir

Audience: HIV/AIDS and cardiological healthcare professionals, patients

[Posted 02/23/2010]

FDA notified healthcare professionals and patients that it is reviewing clinical trial data about a potentially serious effect on the heart from the use of Invirase (saquinavir) in combination with Norvir (ritonavir), antiviral medications given together to treat HIV infection.

The data suggest that together the two drugs may affect the electrical activity of the heart, known as prolonged QT or PR intervals. A prolonged QT interval can increase the risk for a serious abnormal rhythm called torsades de pointes. A prolonged PR interval can cause the electrical signal responsible for generating a heart beat to slow or even stop, known as heart block.

FDA's analysis of these data is ongoing. The agency will update the public as soon as this review is complete. However, healthcare professionals should be aware of this potential risk for changes to the electrical activity of the heart. Invirase and Norvir should not be used in patients already taking medications known to cause QT interval prolongation such as Class IA (such as quinidine,) or Class III (such as amiodarone) antiarrhythmic drugs, or in patients with a history of QT interval prolongation.

Patients should not stop taking their prescribed antiviral medications. Patients who are concerned about possible risks associated with using Invirase and Norvir should talk to their healthcare professional.