

Saquinavir

Possible association with abnormal heart rhythms

USA. The US FDA notified health-care professionals and patients that it is reviewing clinical trial data suggesting that saquinavir in combination with ritonavir may cause prolongation of the QT and PR intervals. Prolongation of the QT interval may lead to the torsades de pointes. Prolongation of the PR interval may also lead to heart block. Saquinavir is an antiretroviral medication that is used in combination with ritonavir and other antiretroviral medicines to treat HIV infection in adults.

When saquinavir boosted with ritonavir (1000mg/100mg) was given to healthy patients aged 18 to 55 years old, there was a dose-dependent prolongation of the QT and PR intervals. The magnitude of the effect and clinical implications of QT and PR interval prolongation are still being reviewed by the Agency.

Health-care professionals are advised to be aware of this potential risk for changes to the electrical activity of the heart. Saquinavir and ritonavir 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, pre-existing conduction system disease, ischemic heart disease, cardiomyopathy, or underlying structural heart disease.

Reference:

1. WHO Pharmaceuticals Newsletter No. 2, 2010 Page 9
2. Safety Information, US FDA 23 February 2010 (www.fda.gov).

Any such reports in your practice? Have you noted the same or similar Adverse Drug Reactions? If yes, please report to:

The Pharmacovigilance Department, Pharmacy and Poisons Board.

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***"You need not be certain...
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