



Summary of investigation results

Efavirenz

Non-proprietary name

Efavirenz

Brand name (Marketing authorization holder)

Stocrin Tablets 200 mg, 600 mg (MSD K. K.)

Indications

HIV-1 infection

Summary of revision

“Prolonged QT” should be added to the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Prolonged QT interval was observed in conjunction with increased blood concentration of efavirenz in an overseas clinical study investigating the effect of this drug on the QT interval. Several cases of prolonged QT have also been reported in patients treated with efavirenz overseas. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

No cases involving prolonged QT have been reported.