



Summary of Investigation Results

Efavirenz

March 15, 2022

Non-proprietary name

Efavirenz

Brand name (Marketing authorization holder)

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

Indications

HIV-1 infection

Summary of revisions

“Psychoneurotic symptoms” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of psychoneurotic symptoms have been reported in patients treated with efavirenz in Japan and overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.



This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases involving psychoneurotic symptoms have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).