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Translated by
Pharmaceuticals and Medical Devices Agency



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

Revision of Precautions

Efavirenz

March 15, 2022

Therapeutic category

Anti-virus agents

Non-proprietary name

Efavirenz

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Psychoneurotic symptoms</u></p> <p><u>Ataxia, encephalopathy, coma, confusion, psychomotor slowing, psychosis, delirium, convulsions, epileptic seizures, etc. may occur.</u></p> <p><u>Cases of these symptoms that developed several months to several years following initiation of this drug have been reported.</u></p>

N/A: Not Applicable. No corresponding language is included in the current package insert.

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