



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

Cladribine

April 19, 2018

Non-proprietary name

Cladribine

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following language should be added (revised language is underlined):

Progressive multifocal leukoencephalopathy (PML):

Progressive multifocal leukoencephalopathy (PML) may occur. Patients should be closely monitored during and after being treated with this drug. If symptoms such as disturbed consciousness, cognitive disorder, symptoms of paralysis (hemiplegia or quadriplegia), language disorder, or visual disturbance are observed, imaging diagnostic assessment using MRI and cerebrospinal fluid tests should be performed. In addition, administration of this drug should be discontinued, and appropriate measures should be taken.

*This drug is designated as a drug requiring preparation of a Drug Guide for Patients.