



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

Lenalidomide hydrate

January 10, 2019

Non-proprietary name

Lenalidomide hydrate

Safety measure

Precautions should be revised in the package insert.

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

Progressive multifocal leukoencephalopathy (PML):

Progressive multifocal leukoencephalopathy (PML) may occur. Patients should be closely monitored during and after the administration of this drug. If symptoms such as disturbed consciousness, cognitive disorder, symptoms of paralysis (hemiplegia or quadriplegia), or disorders related to linguistic capacity are observed, administration of this drug should be discontinued, diagnostic assessment using MRI and cerebrospinal fluid tests should be performed, and other measures should be taken as appropriate.