

Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results Cladribine

April 19, 2018

Non-proprietary name

Cladribine

Brand name (marketing authorization holder)

Leustatin Injection 8 mg (Janssen Pharmaceutical K.K.)

Indications

Hairy cell leukemia

Recurrent, relapsing, or refractory indolent B-cell non-Hodgkin's lymphoma including follicular lymphoma, and mantle cell lymphoma

Summary of revision

"Progressive multifocal leukoencephalopathy" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of progressive multifocal leukoencephalopathy have been reported in patients treated with cladribine including cases reported overseas during the previous 3 fiscal years. Based on the results of their investigation of the currently available evidence and in consultation with expert advisors, MHLW/PMDA concluded that revision of the package insert was necessary.

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

No cases associated with progressive multifocal leukoencephalopathy have been reported during the previous 3 fiscal years.

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