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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Methotrexate

October 12, 2022

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Antimetabolic agents

Non-proprietary name

Methotrexate

Safety measure

Precautions should be revised.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Progressive multifocal leukoencephalopathy (PML):</u> <u>Progressive multifocal leukoencephalopathy (PML) may occur. Patients should be carefully monitored during and after the treatment with this drug. If symptoms such as disturbed consciousness, cognitive disorder, paralytic symptoms (hemiplegia or quadriplegia), dyslalia, or speech loss are observed, diagnostic imaging through MRI and cerebrospinal fluid test should be performed, administration should be discontinued, and appropriate measures should be taken.</u>

Note: Designated as a drug requiring preparation of a Drug Guide for Patients

(N/A) Not Applicable. No corresponding language is included in the current Precautions.

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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Progressive multifocal leukoencephalopathy (PML)</u> <u>Patients should be carefully monitored during and after the treatment</u>

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	with this drug. If symptoms such as disturbed consciousness, cognitive disorder, paralytic symptoms (hemiplegia or quadriplegia), dyslalia, or speech loss are observed, diagnostic imaging through MRI and cerebrospinal fluid test should be performed, administration should be discontinued, and appropriate measures should be taken.

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