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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Cytarabine (excluding 400 mg and 1 g preparations)

October 6, 2020

Therapeutic category

Antimetabolic agents

Non-proprietary name

Cytarabine

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Eye symptom and cutaneous symptom are known characteristic adverse reactions to this drug. Eye symptom includes conjunctivitis, eye pain, photophobia, eye discharge, conjunctival hyperaemia, and corneal ulcer. These symptoms may be prevented or reduced with corticosteroid ophthalmic solution. Cutaneous symptom includes rash, redness, and erythema (frequently accompanied by intense pain) in the distal portion of the extremities. These symptoms may be reduced with corticosteroid.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Cytarabine syndrome</u> <u>Cytarabine syndrome may occur as pyrexia, muscle pain, bone pain and occasionally as rash maculo-papular, chest pain, conjunctivitis, and malaise. Patients should be carefully monitored. The syndrome usually occurs 6 to 12 hours following administration of this drug. If any of these symptoms occur, appropriate measures should be taken such as administration of corticosteroid.</u>

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13. OVERDOSAGE 13.1 Symptoms Cytarabine syndrome (pyrexia, muscle pain, and bone pain) may occur rarely with high dose administration of this drug.	(deleted)

N/A: Not Applicable, because the section is not included in the current package insert.