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Revision of Precautions

Amenamevir

March 31, 2020

Therapeutic category

Antivirals

Non-proprietary name

Amenamevir

Safety measure

Precautions should be revised in the package insert.

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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 (N/A)	Adverse Reactions <u>Clinically Significant Adverse Reactions</u> <u>Erythema multiforme:</u> <u>Erythema multiforme may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken such as discontinuing this drug.</u>

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
11. ADVERSE REACTIONS (N/A)	11. ADVERSE REACTIONS <u>11.1 Clinically Significant Adverse Reactions</u> <u>Erythema multiforme</u>

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

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