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Revision of Precautions

Eculizumab (genetical recombination)

December 8, 2020

Therapeutic category

Other biological preparations

Non-proprietary name

Eculizumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Serious infection</u> <u>Serious infection such as disseminated gonococcal infection, pneumococcal infection, and haemophilus influenzae infection may occur.</u>

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

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