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Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Anti-human thymocyte immunoglobulin, rabbit

March 27, 2023

Therapeutic category

Other biological preparations

Non-proprietary name

Anti-human thymocyte immunoglobulin, rabbit

Safety measure

Precautions should be revised.

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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
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><Common to all indications></p> <p>When retreatment with this drug for patients who have previously received this drug or other preparations of rabbit serum is absolutely necessary, this drug should be administered under sufficient monitoring by a physician with necessary measures taken prior to treatment, such as confirming whether patients have antibodies to this drug.</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><Common to all indications></p> <p>When retreatment with this drug for patients who have previously received this drug or other preparations of rabbit serum is absolutely necessary, <u>even after considering possible treatments with anti-human thymocyte immunoglobulin preparations derived from other species</u>, this drug should be <u>carefully</u> administered under sufficient monitoring by a physician with necessary measures taken prior to treatment, such as confirming whether patients have antibodies to this drug <u>or preparing for emergency treatment measures</u>.</p>

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