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Translated by  
Pharmaceuticals and Medical Devices Agency



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*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

## Cortisone acetate

January 10, 2024

### **Therapeutic category**

Adrenal hormone preparations

### **Non-proprietary name**

Cortisone acetate

### **Safety measure**

PRECAUTIONS should be revised.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS <u>It has been reported that tumour lysis syndrome occurred when hydrocortisone preparations (injections) were administered to patients with lymphoid tumours. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc.</u></p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Tumour lysis syndrome</u> <u>Tumour lysis syndrome may occur when this drug is administered to patients with lymphoid tumours. If any abnormalities are observed, appropriate measures (e.g., administration of physiological saline solution and/or hyperuricaemia therapeutic agents, and dialysis) should be taken, and patients should be carefully monitored until recovery from such symptoms.</u></p>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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