Revision of PRECAUTIONS

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Non-proprietary name

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Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS Hepatic function tests (clinical symptoms, hepatic enzymes (e.g., γ-GTP, ALT), total bilirubin, etc.) should be performed before administering this product. Patients should undergo hepatic function tests once a week for the first 3 months, and they should be monitored until the test results return to normal levels. Prednisolone should be administered before and after treatment with this product following the descriptions in Table 1 in Section 7.	8. IMPORTANT PRECAUTIONS Hepatic function tests (clinical symptoms, hepatic enzymes (e.g., γ-GTP, ALT), total bilirubin, albumin, activated partial thromboplastin time, prothrombin time, prothrombin time/international normalized ratio, etc.) and imaging tests should be performed before administering this product. If any abnormalities are observed, appropriate measures, such as postponing the administration, should be taken. Patients should undergo hepatic function tests described above once a week for the first 3 months. If any abnormalities are observed, they should be monitored until the test results return to normal levels. Prednisolone should be administered before and after treatment with this product following the descriptions in Table 1 in Section 7.
Administration of corticosteroids may exacerbate infections. Therefore, in patients complicated with infections, administration of this product should be deferred until they recover from the infections or their conditions become controllable.	Administration of corticosteroids may induce infections. Therefore, patients should be closely monitored when they are administered this product, and attention should be paid to the occurrence or exacerbation of the infections.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS
9.1 Patients with Complication or History of Diseases, etc.	9.1 Patients with Complication or History of Diseases, etc.
(N/A)	Patients complicated with infections Administration of corticosteroids may exacerbate infections. Therefore, administration of this product should be deferred until the patients recover from infections or the conditions become controllable.
11. DEFECTS/ADVERSE REACTIONS	11. DEFECTS/ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
Hepatic impairment Serious hepatic impairment accompanied by increases in hepatic enzymes (e.g., γ-GTP, ALT) and total bilirubin may occur. If any abnormalities are observed, appropriate measures, such as continuing the administration of prednisolone, should be taken.	Hepatic impairment, acute hepatic failure Serious hepatic impairment accompanied by increases in hepatic enzymes (e.g., γ-GTP, ALT) and total bilirubin may occur. If any abnormalities are observed, appropriate measures, such as continuing the administration of prednisolone, should be taken. Cases of acute hepatic failure resulting in death after administration of this product have been reported overseas (in non-ambulatory patients).

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