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Pharmaceuticals and Medical Devices Agency

Revision of Precautions
Tocilizumab (genetical recombination)

September 24, 2019

Therapeutic category

Biological preparations-miscellaneous

Non-proprietary name

Tocilizumab (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, 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 Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions Hepatic impairment: Hepatic impairment associated with increased levels of AST, ALT and bilirubin, etc. may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuing administration should be taken.

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
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.3 Patients with hepatic impairment When administering this drug to patients with active hepatic disease or hepatic impairment, patients should be carefully monitored for an elevation in transaminase levels, etc. If any abnormalities are observed, appropriate measures such as discontinuing administration should be taken.	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.3 Patients with hepatic impairment Patients should be carefully monitored for an elevation in transaminase levels, etc.

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11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Hepatic impairment Hepatic impairment associated with increased levels of AST, ALT and bilirubin, etc. may occur.

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