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Revision of Precautions

Tofacitinib citrate

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Therapeutic category

Miscellaneous metabolism agents

Non-proprietary name

Tofacitinib citrate

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
5. PRECAUTIONS CONCERNING INDICATIONS (N/A)	5. PRECAUTIONS CONCERNING INDICATIONS <Common to all indications> Venous thromboembolism may occur. Alternative treatments should be considered when this drug is administered to patients with risk factors of cardiovascular events.
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. Patients with risk factors of cardiovascular events Alternative treatments should be considered. In particular, it should be carefully determined whether this drug should be administered at a dose of 10 mg twice daily. When this drug is administered, the patients should be carefully monitored for signs and symptoms of venous thromboembolism. Venous thromboembolism may occur. In an ongoing overseas clinical study in patients aged 50 years or older with rheumatoid arthritis and at least 1 risk factor of cardiovascular events (smoking status, hypertension, diabetes mellitus, a history of coronary artery disease, etc.), the incidence of pulmonary embolism and deep vein thrombosis tended to be higher in a dose-dependent manner in

	patients who received 5 mg twice daily and those who received 10 mg twice daily of this drug compared to patients who received TNF inhibitors. It was reported that the incidence of death including sudden cardiac death tended to be similar in patients who received TNF inhibitors and those who received this drug at a dose of 5 mg twice daily while it was higher in patients who received this drug at a dose of 10 mg twice daily.
	11. ADVERSE REACTIONS
11. ADVERSE REACTIONS	11.1 Clinically Significant Adverse Reactions
11.1 Clinically Significant Adverse Reactions	Venous thromboembolism
(N/A)	Pulmonary embolism and deep vein thrombosis may occur.

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