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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

Tofacitinib citrate

August 22, 2019

Therapeutic category

Miscellaneous metabolism agents

Non-proprietary name

Tofacitinib citrate

Safety measure

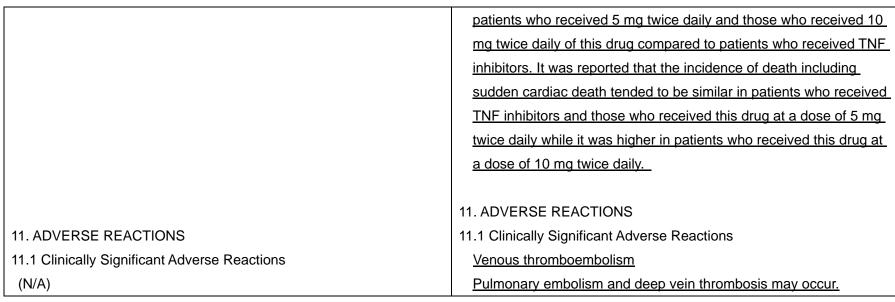
Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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	5. PRECAUTIONS CONCERNING INDICATIONS
(N/A)	<common all="" indications="" to=""></common>
	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	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC
BACGROUNDS	BACKGROUNDS
9.1 Patients with Complication or History of Diseases, etc.	9.1 Patients with Complication or History of Diseases, etc.
(N/A)	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



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