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Translated by Pharmaceuticals and Medical Devices Agency



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 Ticagrelor

March 15, 2022

Therapeutic category Agents relating to blood and body fluids, n.e.c. (not elsewhere classified)

Non-proprietary name

Ticagrelor

Safety measure Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
(N/A)	Bradyarrhythmia such as sinus arrest and an advanced type of
	atrioventricular block

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

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