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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

Clopidogrel sulfate

December 8, 2020

Therapeutic category

Other agents relating to blood and body fluids

Non-proprietary name

Clopidogrel sulfate

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: safety.info@pmda.go.jp

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
<p>Precautions concerning Dosage and Administration</p> <p>For ischaemic heart disease for which percutaneous coronary intervention (PCI) is indicated,</p> <p style="padding-left: 40px;">This drug should be co-administered with aspirin (81-100 mg/day)</p>	<p>Precautions concerning Dosage and Administration</p> <p>For ischaemic heart disease for which percutaneous coronary intervention (PCI) is indicated,</p> <p style="padding-left: 40px;">This drug should be co-administered with aspirin (81-10 mg/day) <u>during dual anti-platelet therapy (DAPT). The latest Japanese and overseas guidelines or other similar sources should be referred to for the post-DAPT administration.</u></p>

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
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><For ischaemic heart disease for which percutaneous coronary intervention (PCI) is indicated></p> <p style="padding-left: 40px;">This drug should be co-administered with aspirin (81-100 mg/day).</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><For ischaemic heart disease for which percutaneous coronary intervention (PCI) is indicated></p> <p style="padding-left: 40px;">This drug should be co-administered with aspirin (81-100 mg/day) <u>during dual anti-platelet therapy (DAPT). The latest Japanese and overseas guidelines or other relevant sources should be referred to for the post-DAPT administration.</u></p>

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