This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Clopidogrel sulfate, Clopidogrel sulfate/aspirin

April 23, 2015

Non-proprietary name

a. clopidogrel sulfate

b. clopidogrel sulfate/aspirin

Brand name (Marketing authorization holder)

a. Plavix Tablets 25 mg, 75 mg, and the others (Sanofi K.K., and the others)

b. Complavin Combination Tablets (Sanofi K.K., and the others)

Indications

a. Suppression of recurrence after ischaemic cerebrovascular disorder (except cardioembolic stroke)

Following ischaemic heart diseases for which percutaneous coronary intervention (PCI) is indicated:

Acute coronary syndrome (unstable angina, non–ST-segment elevation myocardial infarction, and ST-segment elevation myocardial infarction)

Stable angina pectoris and old myocardial infarction

Inhibition of thrombogenesis/embolization in peripheral arterial disease

b. Following ischaemic heart diseases for which percutaneous coronary intervention (PCI) is indicated:

Acute coronary syndrome (unstable angina, non–ST-segment elevation myocardial infarction, and ST-segment elevation myocardial infarction)

Stable angina pectoris and old myocardial infarction

Summary of revision

a. ‘Acute generalised exanthematous pustulosis’ should be added to the toxic epidermal necrolysis, oculomucocutaneous syndrome, and erythema multiforme exudativum subsection in the Clinically significant adverse reactions section.

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b. 'Acute generalised exanthematous pustulosis' should be added to the toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme exudativum, and dermatitis exfoliative subsection in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with clopidogrel sulfate in Japan and overseas, and the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

a. One case associated with acute generalised exanthematous pustulosis has been reported (a causal relationship was ruled out). The one reported case did not have a fatal outcome.
b. No case associated with acute generalised exanthematous pustulosis has been reported.

NOTE

*CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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