



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/aspirin

April 23, 2015

Non-proprietary name

Clopidogrel sulfate/aspirin

Safety measure

Precautions in the package insert should be revised.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are revised):

Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), acute generalised exanthematous pustulosis, and erythema multiforme exudativum:

Toxic epidermal necrolysis, oculomucocutaneous syndrome, acute generalised exanthematous pustulosis, and/or erythema multiforme exudativum may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.