



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

April 23, 2015

Non-proprietary name

Clopidogrel sulfate

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), erythema multiforme exudativum, and acute generalised exanthematous pustulosis:

Toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme exudativum, and/or acute generalised exanthematous pustulosis 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.