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.