



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 Ceftriaxone sodium hydrate

October 20, 2015

Non-proprietary name

Ceftriaxone sodium hydrate

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection regarding toxic epidermal necrolysis and oculomucocutaneous syndrome of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens–Johnson syndrome), and acute generalised exanthematous pustulosis:

Toxic epidermal necrolysis, oculomucocutaneous syndrome, 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 adopted.