



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

Azithromycin hydrate (tablets, capsules for pediatric use, granules for pediatric use, injections)

August 3, 2017

Non-proprietary name

Azithromycin hydrate (tablets, capsules for pediatric use, granules for pediatric use, injections)

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text regarding toxic epidermal necrolysis and mucocutaneous-ocular syndrome should be revised (underlined parts are revised):

Toxic epidermal necrolysis (TEN), mucocutaneous-ocular syndrome (Stevens-Johnson syndrome), and acute generalized exanthematous pustulosis:

Toxic epidermal necrolysis, mucocutaneous-ocular syndrome, acute generalized exanthematous pustulosis may occur. If any abnormalities are observed, administration should be discontinued and appropriate measures including the administration of adrenal corticosteroid should be taken.

These adverse reactions have occurred during administration of the drug or within one week after the end of administration. Careful attention should be paid after the end of administration as well.

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