



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

Doxycycline hydrochloride hydrate

Aug 6, 2014

Non-proprietary Name

Doxycycline hydrochloride hydrate

Safety measure

Precautions should be revised in the package inserts.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added:

Drug-induced hypersensitivity syndrome:

Rash and/or pyrexia may occur as initial symptoms followed by serious late-onset hypersensitivity symptoms with hepatic dysfunction, lymphadenopathy, increased white blood cells, increased eosinophils, and appearance of atypical lymphocytes. Patients should be carefully monitored. If these symptoms are observed, administration of this drug should be discontinued, and appropriate measures should be taken. Signs and symptoms such as rash, pyrexia, and/or hepatic dysfunction may relapse or be prolonged even after discontinuing administration. Therefore, caution should be exercised.

NOTE

- See Drug-induced hypersensitivity syndrome section in Manuals for management of individual serious adverse drug reactions by Ministry of Health, Labour and Welfare