



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

Hydroxyzine hydrochloride, Hydroxyzine pamoate

August 6, 2015

Non-proprietary name

- a. Hydroxyzine hydrochloride
- b. Hydroxyzine pamoate

Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following text should be added (underlined parts are revised):

Patients with prolonged QT interval (including those with long QT interval syndrome congenital), patients being administered drugs known to prolong QT interval, and patients with significant bradycardia or hypokalaemia

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following text should be added (underlined parts are revised):

QT interval prolongation and ventricular tachycardia (including torsades de pointes):
QT interval prolongation or ventricular tachycardia (including torsades de pointes) 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.

NOTE

- This drug is designated to prepare a Drug Guide for Patients.