



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

Amiodarone hydrochloride

June 5, 2018

Non-proprietary name

Amiodarone hydrochloride

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Agranulocytosis, leukopenia:

Agranulocytosis and/or leukopenia may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures, such as discontinuation of administration, should be taken.

*The injectable dosage form of this drug is designated as a drug requiring preparation of a Drug Guide for Patients.