



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

Pentamidine isetionate

April 23, 2014

Non-proprietary Name

Pentamidine isetionate

Safety measure

PRECAUTIONS sections should be revised in a package insert.

In Adverse Reactions (clinically significant adverse reactions) section, information on hypotension, prolonged QT interval, and ventricular arrhythmia should be revised to include the following text (underlines are added):

Hypotension, prolonged QT interval, ventricular arrhythmia, and/or severe bradycardia: Severe hypotension, prolonged QT interval, and/or ventricular arrhythmia (including torsades de pointes) may occur. If these symptoms are observed, administration of this drug should be discontinued immediately and permanently. Severe bradycardia may also occur. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

NOTE

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