



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

Sugammadex sodium

Aug 6, 2014

Non-proprietary Name

Sugammadex sodium

Safety measure

Precautions should be revised in the package inserts.

- In Clinically significant adverse reactions subsection of Adverse Reactions section, texts regarding severe bradycardia should be revised to the following texts (underlined parts are added):

Ventricular fibrillation, ventricular tachycardia, cardiac arrest, and/or severe bradycardia:
Ventricular fibrillation, ventricular tachycardia, cardiac arrest, and/or severe bradycardia may occur within a few minutes after injection of this drug. Patients should be carefully monitored for haemodynamics. If any abnormalities are observed, appropriate measures should be taken.

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

Arteriospasm coronay:

Arteriospasm coronary may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken immediately.