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