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.

Summary of investigation results

Sugammadex sodium

Aug 6, 2014

Non-proprietary Name

Sugammadex sodium

Brand Name (Marketing Authorization Holder)

BRIDION intravenous injection 200 mg and 500 mg (MSD K.K.)

Indications

Reverse the effect of the muscle relaxants rocuronium bromide and vecuronium bromide

Summary of revision

- 'Arteriospasm coronary' should be added in Clinically significant adverse reactions section.
- 'Ventricular fibrillation' and 'ventricular tachycardia' should be added in Cardiac arrest and severe bradycardia subsection of Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of arteriospasm coronary, ventricular fibrillation or ventricular tachycardia have been reported in patients treated with sugammadex in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

A total of 4 cases associated with arteriospasm coronary has been reported. A causal relationship with sugammadex could not be ruled out in all of the 4 cases. No fatalities has been reported.
A total of 5 cases associated with ventricular fibrillation or ventricular tachycardia has been reported. A causal relationship could not be ruled out in all of the 5 cases. No fatalities have been reported.

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