This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Laninamivir octanoate hydrate

August 3, 2017

Non-proprietary name

Laninamivir octanoate hydrate

Brand name (Marketing authorization holder)

Inavir Dry Powder Inhaler 20 mg (Daiichi Sankyo Company, Limited)

Indications

Treatment and prophylaxis of influenza A and B virus infection

Summary of revision

1. A description regarding reported cases of bronchial spasm and decreased respiratory function observed after administration of the product should be newly added in the Important Precautions section.

2. "Bronchial spasm, dyspnoea" should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of bronchial spasm and dyspnoea have been reported in patients treated with laninamivir octanoate hydrate in Japan. Following investigation results based on opinions of the expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

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A total of 8 cases associated with bronchial spasm and dyspnoea have been reported (including 3 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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