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# 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



# Pharmaceuticals and Medical Devices Agency

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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.