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*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

## Laninamivir octanoate hydrate

August 3, 2017

### Non-proprietary name

Laninamivir octanoate hydrate

### Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text regarding bronchospasm and decreased respiratory function in similar drugs should be revised (underlined parts are revised):

Respiratory tract hypersensitivity may increase due to influenza virus infection. Cases of bronchial spasm and decreased respiratory function after administration of this product have been reported. Careful monitoring is necessary when this product is administered to patients with chronic respiratory diseases including bronchial asthma and chronic obstructive pulmonary disease.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Bronchial spasm, dyspnoea:

Careful monitoring should be performed because bronchial spasm and dyspnoea may occur. If any abnormalities are observed, appropriate measures should be taken.