



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, Zanamivir hydrate

August 6, 2015

Non-proprietary name

- a. Laninamivir octanoate hydrate
- b. Zanamivir hydrate

Safety measure

Precautions should be revised in the package insert.

The Careful administration section should be newly added in the package insert. In this new Careful administration section, the following text should be added (underlined parts are revised):

Patients with a history of hypersensitivity to milk products

In the Important Precautions section, the following text should be added (underlined parts are revised):

This drug is using the lactose hydrate which contains milk proteins. There have been reports of anaphylaxis upon administration of this drug to patients with a history of hypersensitivity to milk products. Therefore, caution should be exercised when administering this drug to such patients.