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, Zanamivir hydrate

August 6, 2015

Non-proprietary name

a. Laninamivir octanoate hydrate

b. Zanamivir hydrate

Brand name (Marketing authorization holder)

a. Inavir Dry Powder Inhalers 20 mg (Daiichi Sankyo Company, Limited)

b. Relenza (GlaxoSmithKline K.K.)

Indications

a. Treatment and prophylaxis of influenza A or B virus infections

b. Treatment and prophylaxis of influenza A or B virus infections

Summary of revision

1. "Careful administration" section should be newly added in the package insert. In addition, "Patients with a history of hypersensitivity to milk products" should be added in the new Careful administration section.
2. An alert regarding patients with allergy to milk products should be newly added in the Important precautions section.

Background of the revision and investigation results

Cases of anaphylaxis have been reported among patients with allergy to milk products being treated with laninamivir octanoate hydrate and zanamivir hydrate in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

a. A total of 5 cases* associated with anaphylaxis have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). Of the 5 cases, no fatality has been reported.
b. A case* associated with anaphylaxis has been reported (a causal relationship to the product could not be ruled out for the patient). The one reported case did not have a fatal outcome.

NOTE

*Patients with allergy to milk products

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