



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 Sitagliptin phosphate hydrate Vildagliptin, Vildagliptin/Metformin hydrochloride

April 21, 2016

Non-proprietary name

- a. Sitagliptin phosphate hydrate
- b. Vildagliptin
- c. Vildagliptin/Metformin hydrochloride

Safety measure

Precautions should be revised in the package insert.

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

Pemphigoid

Pemphigoid may occur. If blister, erosion or other signs and symptoms are observed, patients should be referred to a dermatologist, and appropriate measures such as discontinuation of administration should be adopted.