



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 Sodium chloride/Potassium chloride/ Sodium sulfate anhydrous/ Macrogol 4000/Ascorbic acid/ Sodium L-ascorbate

April 21, 2016

Non-proprietary name

Sodium chloride/Potassium chloride/Sodium sulfate anhydrous/Macrogol 4000/Ascorbic acid/Sodium L-ascorbate

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):

Syncope and loss of consciousness:

Syncope and loss of consciousness may occur, and there have been reports of cases associated with decreased blood pressure. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be adopted.

For home use, patients should be instructed with reference to “Important precautions” section.

Pharmaceuticals and Medical Devices Agency

Office of Safety I

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

E-mail: safety.info@pmda.go.jp