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 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

Brand name (Marketing authorization holder)

Moviprep Combination Oral Solution (EA Pharma Co., Ltd.)

Indications

Elimination of intestinal contents as pretreatment prior to colonoscopy or large intestine surgery

Summary of revision

“Syncope and loss of consciousness” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of syncope and loss of consciousness have been reported in patients treated with sodium chloride/potassium chloride/sodium sulfate anhydrous/Macrogol 4000/ascorbic acid/sodium L-ascorbate 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 total of 9 cases of syncope or loss of consciousness have been reported (including 6 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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