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

Magnesium oxide

October 20, 2015

Non-proprietary name

Magnesium oxide

Brand name (Marketing authorization holder)

Magmitt Tablets 200 mg, 250 mg, 330 mg, and 500 mg, Magmitt Fine Granules 83% (Kyowa Chemical Industry Co., Ltd.) and the others

Indications

Improvement of antacid actions and symptoms in the following diseases:

Gastroduodenal ulcer, gastritis (including acute/chronic gastritis and drug-induced gastritis), gastrointestinal dysfunction (including anorexia nervosa, so-called gastroptosis, and hyperchlorhydria)

Constipation

Prevent the formation of calcium oxalate urinary stone

Summary of revision

1. “Geriatrics” should be added in the Careful administration section.
2. The following precautions regarding hypermagnesemia should be added in the Important precautions section:
   - Use of the product should be kept to a minimum.
   - Patients should be instructed to seek medical attention if they experience any symptoms.
3. Precautions regarding hypermagnesemia should be added in the “Use in geriatrics” section.

Background of the revision and investigation results

Cases of hypermagnesaemia have been reported in patients treated with magnesium oxide in Japan.

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(1) In geriatrics, many cases have been reported in which hypermagnesaemia has led to serious outcomes.
(2) Hypermagnesaemia has been reported in many patients with constipation. In addition, it has been reported that hypermagnesaemia led to serious outcome in some patients, even if the renal function was normal or the dosage was under the recommended dose.
(3) Occurrence of hypermagnesaemia was not detected in many patients until serious outcomes such as loss of consciousness had occurred because periodic measurement of serum magnesium concentration was not conducted for the patients.

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.

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

A total of 29 cases associated with hypermagnesaemia have been reported (including 19 cases for which a causal relationship to the product could not be ruled out). Of the 29 cases, 4 fatal cases have been reported (a causal relationship between the product and the fatal outcome could not be ruled out for 1 of these patients).

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