



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 Magnesium oxide

October 20, 2015

Non-proprietary name

Magnesium oxide

Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following text should be added (underlined parts are revised):

Geriatrics

In the Important precautions section, the following text should be revised (underlined parts are revised):

Hypermagnesaemia may occur. In particular, in patients with constipation, 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. Therefore, caution should be exercised for the following points.

- (1) Use of the drug should be kept to a minimum.
- (2) If this drug is administered for a prolonged period or for geriatrics, special precautions such as periodic measurement of serum magnesium concentration should be taken.
- (3) If symptoms such as vomiting, bradycardia, muscular weakness, and somnolence are observed, patients should be instructed to discontinue this drug and seek medical attention immediately.



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In the Use in geriatrics section, the following text should be revised (underlined parts are revised):

In geriatrics, many cases have been reported in which hypermagnesaemia has led to serious outcomes. The dose should be reduced, and patients should be carefully monitored with periodic measurement of serum magnesium concentration, etc.

NOTE

- This drug is designated to prepare a Drug Guide for Patients.