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Revision of Precautions

Esomeprazole Magnesium Hydrate

February 16, 2016

Non-proprietary name

Esomeprazole Magnesium Hydrate

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):

> Rhabdomyolysis:
> Rhabdomyolysis may occur. Patients should be carefully monitored. If symptoms including myalgia, feeling of weakness, increased creatinine kinase (creatine phosphokinase), or increased blood and urine myoglobin are observed, administration of this drug should be discontinued and appropriate measures should be adopted.

*Esomeprazole magnesium hydrate is designated as a drug requiring preparation of a Drug Guide for Patients.

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