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Revision of Precautions

Amoxicillin hydrate, vonoprazan fumarate/amoxicillin hydrate/clarithromycin, vonoprazan fumarate/amoxicillin hydrate/metronidazole, rabeprazole sodium/amoxicillin hydrate/clarithromycin, rabeprazole sodium/amoxicillin hydrate/metronidazole, lansoprazole/amoxicillin hydrate/clarithromycin, lansoprazole/amoxicillin hydrate/metronidazole

October 17, 2017

Non-proprietary name

Amoxicillin hydrate, vonoprazan fumarate/amoxicillin hydrate/clarithromycin, vonoprazan fumarate/amoxicillin hydrate/metronidazole, rabeprazole sodium/amoxicillin hydrate/clarithromycin, rabeprazole sodium/amoxicillin hydrate/metronidazole, lansoprazole/amoxicillin hydrate/clarithromycin, lansoprazole/amoxicillin hydrate/metronidazole

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be revised (underlined parts are revised):

Granulocytopenia, <u>thrombocytopenia:</u>

Granulocytopenia or <u>thrombocytopenia</u> may occur. Patients should be carefully monitored by means such as periodically performing tests. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

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* Vonoprazan fumarate/amoxicillin hydrate/metronidazole is designated as a drug requiring preparation of a Drug Guide for Patients.

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