Revision of PRECAUTIONS
Lansoprazole/Amoxicillin hydrate/Metronidazole, Rabeprazole sodium/Amoxicillin hydrate/Metronidazole

Aug 6, 2014

Non-proprietary Name
• Lansoprazole/Amoxicillin hydrate/Metronidazole
• Rabeprazole sodium/Amoxicillin hydrate/Metronidazole

Safety measure
Precautions should be revised in the package inserts.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added:

Haemorrhagic colitis:
Haemorrhagic colitis may occur. If symptoms such as abdominal pain, bloody stool, and frequent diarrhea are observed, administration of this drug should be discontinued immediately, and appropriate measures should be taken.

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