Revision of PRECAUTIONS

Metronidazole

Aug 6, 2014

Non-proprietary Name
Metronidazole (oral dosage form)

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 when metronidazole is used for treatment of Helicobacter pylori infection. If abdominal pain, bloody stool, 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.