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Revision of Precautions

Metronidazole (oral and injectable dosage forms)

Vonoprazan fumarate/amoxicillin hydrate/metronidazole

Rabeprazole sodium/amoxicillin hydrate/metronidazole

Lansoprazole/amoxicillin hydrate/metronidazole

June 5, 2018

Non-proprietary name

Metronidazole (oral and injectable dosage forms)

Vonoprazan fumarate/amoxicillin hydrate/metronidazole

Rabeprazole sodium/amoxicillin hydrate/metronidazole

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Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Careful Administration section (revised

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language is underlined):

Patients with Cockayne's syndrome

The following language should be added to the Important Precautions section (revised language is underlined):

Hepatic impairment may occur. Patients should be carefully monitored through methods such as periodic examinations.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Hepatic impairment:
Hepatic impairment may occur. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken. Severe hepatotoxicity or acute hepatic failure resulting in mortality has been reported in patients with Cockayne's syndrome.

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