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Revision of Precautions

Amoxicillin hydrate, potassium clavulanate/amoxicillin hydrate, rabeprazole sodium/amoxicillin hydrate/clarithromycin, rabeprazole sodium/amoxicillin hydrate/metronidazole lansoprazole/amoxicillin hydrate/clarithromycin, lansoprazole/amoxicillin hydrate/metronidazole,

January 9, 2015

Non-proprietary Name

- amoxicillin hydrate
- potassium clavulanate/amoxicillin hydrate
- 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.

Information on toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome, erythema multiforme, and acute generalised exanthematous pustulosis in the Clinically significant adverse reactions subsection of the Adverse reactions section should be revised as follows (underlined parts are revised):

TEN, oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme, acute generalised exanthematous pustulosis, and erythroderma (dermatitis exfoliative):
TEN, oculomucocutaneous syndrome, erythema multiforme, acute generalised exanthematous pustulosis, and erythroderma (dermatitis exfoliative) may occur. Patients should be carefully monitored. If any abnormalities such as pyrexia, headache, arthralgia, erythema/blister of the skin and mucous membranes, pustules, feeling tension/burning sensation/pain of skin are observed, administration of this drug should be discontinued and appropriate measures should be taken.

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The following texts should be added (underlined parts are revised):

Meningitis aseptic:
Meningitis aseptic with symptoms including nuchal rigidity, pyrexia, headache, nausea/vomiting, or consciousness clouding may occur. If these symptoms are observed, administration of this drug should be discontinued and appropriate measures should be taken.

NOTE

- Rabeprazole sodium/amoxicillin hydrate/clarithromycin is designated to prepare a Drug Guide for Patients.

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