



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions Roxithromycin

October 20, 2015

Non-proprietary name

Roxithromycin

Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following text should be added (underlined parts are revised):

Patients with risk of prolonged QT (patients with congenital long QT syndrome, patients with abnormal electrolytes such as hypokalemia, and patients who are receiving drugs known to cause prolonged QT)

In the Clinically significant adverse reaction subsection regarding haemorrhagic colitis of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Pseudomembranous colitis, haemorrhagic colitis:

Serious colitis such as pseudomembranous colitis or haemorrhagic colitis may occur.

If abdominal pain, frequent diarrhea, or bloody stool is observed, appropriate measures such as immediate discontinuation of administration should be adopted.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

QT prolonged, ventricular tachycardia (including torsades de pointes):

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Prolonged QT or ventricular tachycardia (including torsades de pointes) may occur.
Patients should be carefully monitored. If any abnormalities are observed, administration
of this drug should be discontinued and appropriate measures should be adopted.