Summary of investigation results

Roxithromycin

October 20, 2015

Non-proprietary name

Roxithromycin

Brand name (Marketing authorization holder)

Rulid Tablets 150 (Sanofi K.K.) and the others

Indications

Applicable microorganisms:

Roxithromycin-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, *Pneumococcus*, *Moraxella* (*Branhamella*) *catarrhalis*, *Propionibacterium acnes*, and *Mycoplasma pneumoniae*

Applicable conditions:

Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, acne (associated with purulent inflammation), pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, otitis media, sinusitis, periodontal inflammation, pericoronitis, and jaw inflammation

Summary of revision

1. “Patients with risk of prolonged QT” should be added in the Careful administration section.
2. The following should be added in the Clinically significant adverse reaction section:
   (1) “pseudomembranous colitis”
   (2) “QT prolonged and ventricular tachycardia (including torsades de pointes)”

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

Background of the revision and investigation results

Cases of pseudomembranous colitis and QT prolonged and ventricular tachycardia (including torsades de pointes) have been reported in patients treated with roxithromycin both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

1. No case associated with pseudomembranous colitis has been reported.
2. No case associated with QT prolonged and ventricular tachycardia has been reported.

NOTE:

*CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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