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.

Summary of investigation results

Sitafloxacin hydrate

August 4, 2016

Non-proprietary name

Sitafloxacin hydrate

Brand name (Marketing authorization holder)

Gracevit Tablets 50 mg, Gracevit Fine Granules 10% (Daiichi Sankyo Company, Limited).

Indications

(Applicable microorganisms)

Sitafloxacin hydrate-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, genus *Pneumococcus*, genus *Enterococcus*, *Moraxella (Branhamella) catarrhalis*, *Escherichia coli*, genus *Citrobacter*, genus *Klebsiella*, genus *Enterobacter*, genus *Serratia*, genus *Proteus*, *Morganella morganii*, *Haemophilus influenzae*, *Pseudomonas aeruginosa*, *Legionella pneumophila*, genus *Peptostreptococcus*, genus *Prevotella*, genus *Porphyromonas,* genus *Fusobacterium*, *Chlamydia trachomatis*, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae.*

(Applicable conditions)

- Pharyngitis/laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, and secondary infection of chronic respiratory lesions
- Cystitis, pyelonephritis, and urethritis
- Cervicitis
- Otitis media and sinusitis
- Periodontal inflammation, pericoronitis, and jaw inflammation

Summary of revision

1. “Thrombocytopenia” should be newly added in the Clinically significant adverse reaction section.

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2. “Psychiatric symptoms including confusion, delirium, and hallucination” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of thrombocytopenia and psychiatric symptoms including confusion, delirium, and hallucination have been reported in patients treated with sitafloxacin hydrate in Japan. 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. A total of 2 cases associated with thrombocytopenia have been reported (a causal relationship to the product could not be established for these patients). No fatality has been reported.
2. A case associated with psychiatric symptoms has been reported (a causal relationship to the product could not be ruled out for this patient). No fatality has been reported.

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