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

Moxifloxacin hydrochloride (oral dosage form)

October 17, 2017

Non-proprietary name

Moxifloxacin hydrochloride (oral dosage form)

Brand name (Marketing authorization holder)

Avelox Tablets 400 mg (Bayer Yakuhin, Ltd.)

Indications

Applicable microorganisms:

Moxifloxacin hydrate-susceptible strains of genus *Staphylococci,* genus *Streptococci,* genus *Pneumococci, Moraxella (Branhamella) catarrhalis, Escherichia coli,* genus *Klebsiella,* genus *Enterobacter,* genus *Proteus, Haemophilus influenzae, Legionella pneumophila, Propionibacterium acnes, Chlamydia pneumoniae, and Mycoplasma pneumoniae*

Applicable conditions:

Superficial skin infection, deep-seated skin infection, secondary infections of traumatic injury, thermal burn, surgical wound, and others, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, secondary infection of chronic respiratory lesions, sinusitis

Summary of revision

“Rhabdomyolysis” should be added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with moxifloxacin hydrochloride in Japan. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert of moxifloxacin hydrochloride was necessary.

Pharmaceuticals and Medical Devices Agency
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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan (in and after FY 2014)

A total of 2 cases associated with rhabdomyolysis have been reported (the causal relationship to the product could not be ruled out in those patients). No fatality has been reported.

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