



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

Moxifloxacin hydrochloride (oral dosage form)

October 17, 2017

Non-proprietary name

Moxifloxacin hydrochloride (oral dosage form)

Safety measure

Precautions should be revised in the package insert.

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

Rhabdomyolysis:

Rhabdomyolysis may occur. Patients should be carefully monitored, and if myalgia, feeling of weakness, increased creatinine kinase (creatinine phosphokinase), increased blood and urinary myoglobin, etc. are observed, administration of this drug should be discontinued and appropriate measures should be taken. Attention should be paid to the onset of acute kidney injury due to rhabdomyolysis.