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Translated by Pharmaceuticals and Medical Devices Agency



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 Ciprofloxacin

Ciprofloxacin hydrochloride hydrate

September 24, 2019

Therapeutic category

Synthetic antibiotics

Non-proprietary name

Ciprofloxacin Ciprofloxacin hydrochloride hydrate

Safety measure Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions	Adverse Reactions
Clinically Significant Adverse Reactions	Clinically Significant Adverse Reactions
Tendon disorders such as Achilles tendonitis and tendon rupture:	Tendon disorders such as Achilles tendonitis and tendon rupture:
Tendon disorders such as Achilles tendonitis and tendon rupture	Tendon disorders such as Achilles tendonitis and tendon rupture
may occur. If pain or inflammation in the tendon is observed,	may occur. If symptoms such as pain, edema, and redness around
administration of this drug should be discontinued and appropriate	the tendon are observed, administration of this drug should be
measures should be taken. Cases of these symptoms that	discontinued and appropriate measures should be taken. Cases of
developed several months after the termination of this drug have	these symptoms that developed several months after the
been reported overseas.	termination of this drug have been reported overseas.

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