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Pharmaceuticals and Medical Devices Agency

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

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

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