

FDA Drug Safety Communication

FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together

Safety Announcement

[05-12-2016] The U.S. Food and Drug Administration is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

As a result, we are requiring the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. We are continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.

Patients should contact your health care professional immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include tendon, joint and muscle pain, a “pins and needles” tingling or pricking sensation, confusion, and hallucinations. Patients should talk with your health care professional if you have any questions or concerns.

Health care professionals should stop systemic fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient’s treatment course.

Fluoroquinolone drugs work by killing or stopping the growth of bacteria that can cause illness (see **List of Currently Available FDA-approved Fluoroquinolones for Systemic Use**).

List of Currently Available FDA-approved Fluoroquinolone Antibacterial Drugs for Systemic Use

Brand Name	Active Ingredient
Avelox	Moxifloxacin ⁺
Cipro	Ciprofloxacin ⁺
Cipro extended-release*	Ciprofloxacin extended-release ⁺
Factive	Gemifloxacin ⁺
Levaquin	Levofloxacin ⁺
Moxifloxacin Injection	Moxifloxacin
Ofloxacin*	Ofloxacin

⁺ available as generic

* available only as generic

We previously communicated safety information associated with systemic fluoroquinolone antibacterial drugs in [August 2013](#) and [July 2008](#). The safety issues described in this Drug Safety Communication were also discussed at an [FDA Advisory Committee](#) meeting in November 2015.

We urge patients and health care professionals to report side effects involving fluoroquinolone antibacterial drugs and other drugs to the [FDA MedWatch](#) program, using the information in the “Contact FDA” box at the bottom of the page.

Related Information

The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective
<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>

Thinking it Through: Managing the Benefits and Risks of Medicines
<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143558.htm>

Advisory Committees: Critical to the FDA's Product Review Process
<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143538.htm>