

FDA News Release

FDA updates warnings for fluoroquinolone antibiotics

Limits use for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections

**For Immediate
Release**

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Release

[**Español \(/NewsEvents/Newsroom/ComunicadosdePrensa/ucm516748.htm\)**](#)

The U.S. Food and Drug Administration today approved safety labeling changes for a class of antibiotics, called fluoroquinolones, to enhance warnings about their association with disabling and potentially permanent side effects and to limit their use in patients with less serious bacterial infections.

“Fluoroquinolones have risks and benefits that should be considered very carefully,” said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research. “It’s important that both health care providers and patients are aware of both the risks and benefits of fluoroquinolones and make an informed decision about their use.”

Fluoroquinolones are antibiotics that kill or stop the growth of bacteria. While these drugs are effective in treating serious bacterial infections, an FDA safety review found that both oral and injectable fluoroquinolones are associated with disabling side effects involving tendons, muscles, joints, nerves and the central nervous system. These side effects can occur hours to weeks after exposure to fluoroquinolones and may potentially be permanent.

Because the risk of these serious side effects generally outweighs the benefits for patients with acute bacterial sinusitis, acute exacerbation of chronic bronchitis and uncomplicated urinary tract infections, the FDA has determined that fluoroquinolones should be reserved for use in patients with these conditions who have no alternative treatment options. For some serious bacterial infections, including anthrax, plague and bacterial pneumonia among others, the benefits of fluoroquinolones outweigh the risks and it is appropriate for them to remain available as a therapeutic option.

FDA-approved fluoroquinolones include levofloxacin (Levaquin), ciprofloxacin (Cipro), ciprofloxacin extended-release tablets, moxifloxacin (Avelox), ofloxacin and gemifloxacin (Factive). The labeling changes include an updated Boxed Warning and revisions to the Warnings and Precautions section of the label about the risk of disabling and potentially irreversible adverse reactions that can occur together. The label also contains new limitation-of-use statements to reserve fluoroquinolones for patients who do not have other available treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections. The patient Medication Guide that is required to be given to the patient with each fluoroquinolone prescription describes the safety issues associated with these medicines.

The FDA first added a Boxed Warning to fluoroquinolones in **July 2008 (ssLINK/UCM126085)** for the increased risk of tendinitis and tendon rupture. In February 2011, the risk of worsening symptoms for those with myasthenia gravis was added to the Boxed Warning. In **August 2013 (ssLINK/UCM365050)**, the agency required updates to the labels to describe the potential for irreversible peripheral neuropathy (serious nerve damage).

In November 2015, an **FDA Advisory Committee (ssLINK/UCM424449)** discussed the risks and benefits of fluoroquinolones for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections based on new safety information. The new information focused on two or more side effects occurring at the same time and causing the potential for irreversible impairment. The advisory committee concluded that the serious risks associated with the use of fluoroquinolones for these types of uncomplicated infections generally outweighed the benefits for patients with other treatment options.

Today's action also follows a May 12, 2016, **drug safety communication (/Drugs/DrugSafety/ucm500143.htm)** advising that fluoroquinolones should be reserved for these conditions only when there are no other options available due to potentially permanent, disabling side effects occurring together. The drug safety communication also announced the required labeling updates to reflect this new safety information.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

[Lyndsay Meyer \(mailto:lyndsay.meyer@fda.hhs.gov\)](mailto:lyndsay.meyer@fda.hhs.gov)
 240-402-5345

[Theresa Eisenman \(mailto:theresa.eisenman@fda.hhs.gov\)](mailto:theresa.eisenman@fda.hhs.gov)
 301-796-2969

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Related Information

- **Fluoroquinolone Antimicrobial Drugs Information
(/Drugs/DrugSafety/InformationbyDrugClass/ucm346750.htm)**

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