

Fluoroquinolone Antibacterial Drugs for Systemic Use: Drug Safety Communication - Warnings Updated Due to Disabling Side Effects

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UPDATED 05/10/2017. As part of our ongoing review of fluoroquinolone antibiotics, FDA is informing the public that we have found that cases submitted to the FDA and published in the medical literature to date do not support reports that these medicines may result in detachment of the retina in the eyes, or bulges or tears in the aorta blood vessel called aortic aneurysm and aortic dissection. FDA will continue to assess safety issues with fluoroquinolones and will update the public if additional actions are needed.

Including the following currently available fluoroquinolones

Avelox (moxifloxacin)

Cipro (ciprofloxacin)

Cipro extended-release (ciprofloxacin extended-release)

Factive (gemifloxacin)

Levaquin (levofloxacin)

Ofloxacin (generic brand)

[Posted 07/26/2016]

AUDIENCE: Family Practice, Infectious Disease, Neurology, Pharmacy, Patient

ISSUE: FDA approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection). These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient. As a result, FDA revised the Boxed Warning, FDA's strongest warning, to address these serious safety issues. In addition,

FDA updated other parts of the drug label including the Warnings and Precautions and Medication Guide sections.

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

FDA is continuing to assess safety issues with fluoroquinolones as part of FDA's usual ongoing review of drugs and will update the public if additional actions are needed. See the FDA [Drug Safety Communication](#) for additional information, including a Data Summary and Additional Information for Health Care Professionals and Patients.

BACKGROUND: The labels of fluoroquinolone medicines already have a Boxed Warning for tendinitis, tendon rupture, and worsening of myasthenia gravis. The labels also include warnings about the risks of peripheral neuropathy and central nervous system effects. Other serious risks associated

with fluoroquinolones are described in the labels, such as cardiac, dermatologic, and hypersensitivity reactions. After FDA's 2013 review that led to the additional warning that peripheral neuropathy may be irreversible, FDA evaluated post-marketing reports of apparently healthy patients who experienced disabling and potentially permanent side effects involving two or more body systems after being treated with a systemic fluoroquinolone

RECOMMENDATION: Patients must 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 unusual joint or tendon pain, muscle weakness, a “pins and needles” tingling or pricking sensation, numbness in the arms or legs, confusion, and hallucinations. Talk with your health care professional if you have any questions or concerns (see List of Serious Side Effects from Fluoroquinolones in the FDA [Drug Safety Communication](#)).

Health care professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risks outweigh the benefits in these patients. Stop 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178