

### Fluoroquinolones – Safety Communication

- On July 26, 2016, the [FDA approved](#) changes to the *Boxed Warning*, *Warnings and Precautions*, *Indications and Usage*, and Medication Guide for systemic fluoroquinolones, due to disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient.
- Fluoroquinolones are a class of antibacterial drugs approved to treat or prevent certain bacterial infections.
  - The list of currently available FDA-approved fluoroquinolones for systemic use include: [Avelox<sup>®</sup> \(moxifloxacin\)](#), [Cipro<sup>®</sup> \(ciprofloxacin\)](#), [ciprofloxacin extended-release](#), [Factive<sup>®</sup> \(gemifloxacin\)](#), [Levaquin<sup>®</sup> \(levofloxacin\)](#), and [ofloxacin](#). These fluoroquinolones are available generically.
- The FDA has determined that fluoroquinolones should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) 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.
  - Between November 1997 and May 2015, the FDA identified 178 U.S. cases of apparently healthy patients who took an oral fluoroquinolone to treat ABS, ABECB, or uncomplicated UTIs and developed disabling and potentially irreversible adverse reactions that appeared as a constellation of symptoms.
  - The mean duration of the disabling adverse reactions at the time the report was received was 14 months, with the longest duration reported as 9 years. Several cases reported that select adverse reactions either resolved or improved; other cases reported that the reactions got worse or continued. These adverse reactions may be permanent.
  - Long-term pain of any kind was the most commonly reported symptom, with 97% of all cases reporting pain associated with the musculoskeletal adverse reactions. The ongoing neuropsychiatric adverse reactions were reported to be distressing, affecting employment and quality of life.
- The *Boxed Warning* and *Warnings and Precautions* sections of the label contain information about these serious safety issues.
- The *Indications and Usage* section of the label contains new limitation-of-use statements to reserve fluoroquinolones for patients who do not have other available treatment options for ABS, ABECB, and UTIs.
- Serious side effects from fluoroquinolones include the following:
  - Musculoskeletal and peripheral nervous system: tendinitis, tendon rupture, numbness or tingling or pricking sensation “pins and needles” in arms or legs, muscle weakness, muscle pain, joint pain, and joint swelling.
  - Central nervous system: anxiety, depression, hallucinations, suicidal thoughts, and confusion.

- Other body systems: worsening of myasthenia gravis, skin rash, sunburn, abnormal, rapid or strong heartbeat, and severe diarrhea.
- The safety issues described in this Drug Safety Communication were also discussed at a November 2015 [FDA Advisory Committee meeting](#).
- Healthcare professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for ABS, ABECB, and uncomplicated UTI. In addition, if a patient reports serious side effects, fluoroquinolone treatment should be stopped and switched to a non-fluoroquinolone drug to complete the patient's treatment course.
- Patients should contact their healthcare provider immediately if they experience any serious side effect while taking a fluoroquinolone medicine. Furthermore, before starting a new fluoroquinolone medicine, patients should inform their health care professional if they have previously experienced any serious side effects with another antibiotic.



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