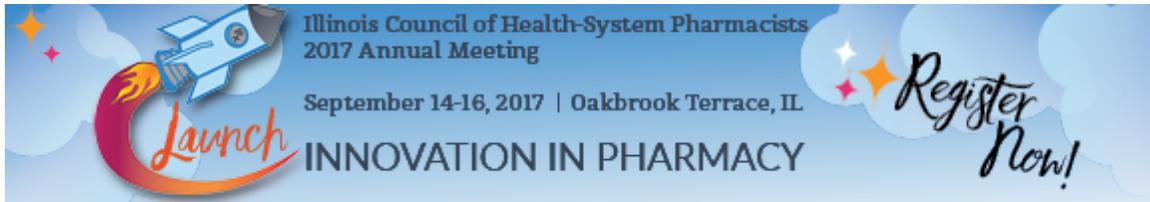




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Professional Affairs Fluoroquinolone Safety

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by Shannon Furbish, PharmD and Janice Richardson, PharmD, BCPS

Shannon Furbish, PharmD
PGY-1 Pharmacy Resident
Captain James A. Lovell Federal Health Care Center

Janice Richardson, PharmD, BCPS
Captain James A. Lovell Federal Health Care Center

In May of 2016, The Food and Drug Administration (FDA) released a drug safety communication addressing fluoroquinolone safety concerns. This warning specifically recommended avoiding the use of fluoroquinolones for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections. Rather, fluoroquinolones should be reserved for more complicated infections. Updates in medication safety labeling were made to emphasize the possible harmful adverse effects associated with fluoroquinolones.¹

Background:

Fluoroquinolones are a broad-spectrum class of antibiotics that includes levofloxacin, ciprofloxacin, moxifloxacin, gemifloxacin, and ofloxacin. Their mechanism of action is inhibition of DNA-gyrase and topoisomerase IV through the formation of a complex with these enzymes, thereby preventing DNA replication. Fluoroquinolones are bactericidal and exhibit concentration-dependent killing. In general, fluoroquinolones have coverage against atypical pathogens such as *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*, gram-negative organisms such as *Pseudomonas aeruginosa*, some gram-positive organisms including *Streptococcus pneumoniae*, and limited anaerobic pathogens (only moxifloxacin). These agents require renal dose adjustments, are well absorbed and exhibit 70-100% bioavailability when taken orally.²

Fluoroquinolones are used for many different types of infections including: urinary tract infections, prostatitis, epididymitis, perioperative antibiotic prophylaxis for transurethral surgery, bronchitis, pneumonia, sinusitis, gastrointestinal infections, and soft tissue infections.² Fluoroquinolone resistance is becoming increasingly prevalent with overuse and longer duration of therapy. Prudent use of fluoroquinolones is especially important in order to preserve the efficacy and utility of these agents for future use.³⁻⁴

Common side effects of fluoroquinolones include headache, insomnia, dizziness, skin rash, nausea, diarrhea, constipation, abdominal pain, dyspepsia, vomiting, and QT prolongation. More rare, but serious adverse effects - which prompted the FDA safety alert - include tendon rupture, myalgia, arthralgia, peripheral neuropathy, confusion, and hallucinations. These effects are potentially permanent and disabling.²

Safety Alert:

The FDA fluoroquinolone safety alert was released after an extensive FDA safety review of adverse event reports. The FDA concluded that the risks of using fluoroquinolones may outweigh their benefits for certain indications given the potential for serious adverse effects. The agency therefore recommends that fluoroquinolones should be reserved for patients who cannot use alternative antibiotics (i.e. penicillin allergic) for the three indications specified in the alert.¹

The FDA issued an additional safety alert in July 2016 which expanded Black Box Warnings to include peripheral neuropathy, central nervous system (CNS) effects, cardiac, dermatologic, and hypersensitivity reactions. This was in addition to the current warnings for tendinitis, tendon rupture, and worsening of myasthenia gravis.⁵

Considerations:

- Patients should contact their health-care professional if they experience a serious adverse effect while taking a fluoroquinolone. Serious adverse effects may 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.^{1,5}
- Health-care professionals should immediately discontinue fluoroquinolone treatment if a patient reports serious side effects, and switch to an alternative antibiotic for completion of the antibiotic course.^{1,5}
- Health-care professionals should reserve systemic (intravenous or oral) fluoroquinolones for patients who cannot receive alternative preferred treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections.^{1,5}

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