



NATIONAL PBM BULLETIN

JUNE 3, 2016

DEPARTMENT OF VETERANS AFFAIRS
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
VISN PHARMACIST EXECUTIVES (VPEs), AND THE CENTER FOR MEDICAL SAFETY (VA MedSAFE)

FLUOROQUINOLONE SAFETY

I. ISSUE

A Food and Drug Administration (FDA) safety review shows that systemic use (i.e. tablets, capsules, and injectables) of fluoroquinolones is associated with disabling and potentially permanent serious side effects involving the tendons, muscles, joints, nerves, and central nervous system that can occur together. This drug class should be reserved for serious infections, and avoided for upper respiratory tract infections (URI) or uncomplicated urinary tract infections (UTI) unless there is a compelling reason.

II. BACKGROUND

Approved fluoroquinolone drugs include levofloxacin (Levaquin), ciprofloxacin (Cipro), moxifloxacin (Avelox), norfloxacin (Noroxin), ofloxacin (Floxin), and gemifloxacin (Factive).

III. DISCUSSION

FDA continues to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available. FDA will require the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information.

IV. PROVIDER CONSIDERATIONS/RECOMMENDATIONS

FDA recommends that:

- Serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections (UTI) who have other treatment options.
- For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.
- Providers should instruct patients to contact their health care professional immediately if they experience any serious side effects while taking fluoroquinolone medicine such as tendon, joint and muscle pain; a “pins and needles” tingling or pricking sensation; confusion; and hallucinations.
- Providers 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.

Providers should continue to report any adverse reactions with the use of fluoroquinolone medications by entering the information into CPRS’ Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

V. REFERENCES

FDA Drug Safety Communication: FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together. <http://www.fda.gov/Drugs/DrugSafety/ucm500143.htm> (Accessed May 12, 2016).

ACTIONS

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS and Chief Nurse Executives**: Forward this document to all appropriate providers and health care staff (e.g., **primary care providers, infectious disease providers, including contract providers, etc.**). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D**: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).