

Fluoroquinolone Warnings

- ◆ Fluoroquinolones are broad-spectrum antibiotics that are used to treat a variety of infections. They work by blocking the bacteria's DNA replication pathway.
- ◆ Examples of commonly used fluoroquinolones (not all-inclusive):
 - Ciprofloxacin (Cipro), Levofloxacin (Levaquin), Moxifloxacin (Avelox)
- ◆ Over the years, the FDA has issued several drug safety communications for these medications when given systemically (i.e. by mouth or through an injection):
 - **12/20/18:** Increased risk of aortic aneurysm and dissection.
 - The FDA warns that they should not be used in patients at an increased risk unless there are no other treatment options available. They state people at an increased risk include those with a history of blockages or aneurysms of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly.
 - **7/10/18:** Strengthens current warnings in the prescribing information that fluoroquinolones may cause significant decreases in blood sugar and certain mental health side effects.
 - They warn that the low blood sugar can result in serious problems, including coma, **particularly in older people and patients with diabetes who are taking medications to reduce blood sugar.** The FDA is recommending to alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients.
 - Mental health side effects include disturbances in attention, disorientation, agitation, nervousness, memory impairment, and delirium.
 - **7/26/16:** Fluoroquinolones are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system. The Boxed Warning was revised to address these serious safety issues.
 - **5/12/16:** FDA advised that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. The fluoroquinolones should be reserved for use in patients who have no other treatment options for these conditions.
 - **8/15/13:** Requires label changes to warn of the risk of peripheral neuropathy. It can occur at any time during treatment with fluoroquinolones and can last for months to years after the drug is stopped or be permanent.
 - **7/8/08:** Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy.
- ◆ In addition to the above warnings, the fluoroquinolones are associated with QT prolongation, which can put the patient at an increased risk of Torsade de Pointes.
- ◆ As part of your antibiotic stewardship programs, it is important to ensure you're following updated guidelines and using the most narrow antibiotic to which the organisms in question are susceptible. Broad spectrum antibiotics, such as the fluoroquinolones, are associated with an increased risk of C. Difficile infections and antibiotic resistance. If they are to be used, please ensure proper monitoring mechanisms are in place.

References

1. <https://www.fda.gov/Drugs/DrugSafety/ucm628753.htm>
2. Cardiology. 2011;120(2):103-10. doi: 10.1159/000334441. Epub 2011 Dec 13.