

## Fluoroquinolone Antibiotics – Safety communication

- On December 20, 2018, the [FDA announced](#) that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death.
- Fluoroquinolones that are available as brand or generic include [Levaquin® \(levofloxacin\)](#), [Cipro® \(ciprofloxacin\)](#), [ciprofloxacin extended-release tablets](#), [Avelox® \(moxifloxacin\)](#), and [ofloxacin](#). [Baxdela® \(delafloxacin\)](#) is only available as a brand product.
  - Fluoroquinolones have a place in therapy in the treatment of serious bacterial infections which include certain types of bacterial pneumonia or intra-abdominal infections.
  - Consult individual drug labels for specific indication recommendations.
  - The safety updates only affect the oral and injectable fluoroquinolone formulations.
- Fluoroquinolones should not be used in patients at increased risk for aortic aneurysm unless there are no other treatment options available.
  - People at increased risk include those with a history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly.
- A new warning about this risk will be added to the [prescribing information](#) and patient [Medication Guide](#) for all fluoroquinolones.
- Patients should seek medical attention immediately if they experience sudden, severe, and constant pain in the stomach, chest or back.
  - Symptoms of an aortic aneurysm often do not show up until the aneurysm becomes large or bursts, so any unusual side effects from taking fluoroquinolones should be reported to a health care professional immediately.
  - Before starting an antibiotic prescription, patients should inform their health care professional if they have a history of aneurysms, blockages or hardening of the arteries, high blood pressure, or genetic conditions such as Marfan syndrome or Ehlers-Danlos syndrome.
- The FDA reviewed cases submitted to the [FDA's Adverse Event Reporting System \(FAERS\)](#) and four observational studies that showed an increased risk of aortic aneurysm or dissection associated with fluoroquinolone use.
  - The results of all four studies provide consistent evidence of an association between fluoroquinolone use and aortic aneurysm or dissection.
  - The underlying mechanism for this risk cannot be determined from these studies, and the background risk of aortic aneurysm can vary depending on the population.
  - The background risk has been estimated from nine aortic aneurysm events per 100,000 people per year in the general population to 300 aortic aneurysm events per 100,000 people per year in individuals at highest risk.
  - Because multiple studies showed higher rates of about twice the risk of aortic aneurysm rupture and dissection in those taking fluoroquinolones, the FDA determined the warnings were warranted to alert health care professionals and patients.

- The FDA has previously communicated other safety issues associated with fluoroquinolones in [July 2018](#) (significant decreases in blood sugar and certain mental health side effects), [July 2016](#) (disabling side effects of the tendons, muscles, joints, nerves, and central nervous system), [May 2016](#) (restricting use for certain uncomplicated infections), [August 2013](#) (peripheral neuropathy), and [July 2008](#) (tendinitis and tendon rupture).



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