

March 29, 2019



## Drug Safety Communication: Updated Adverse Effects from Fluoroquinolones

Fluoroquinolone antibiotics are approved to treat certain serious bacterial infections and work by killing or stopping the growth of bacteria that can cause illness. Currently available fluoroquinolones are ciprofloxacin, delafloxacin, gemifloxacin, levofloxacin, moxifloxacin, and ofloxacin.

On December 20, 2018, the U.S. Food and Drug Administration (FDA) issued a warning that fluoroquinolones administered orally or intravenously may increase the risk of ruptures of an aortic aneurysm or aortic dissections, which are rare but serious events that can lead to dangerous bleeding or even death. The FDA requires inclusion of the new risks in the prescribing information and patient Medication Guide for all fluoroquinolones.

Health care professionals should not prescribe fluoroquinolones to patients at increased risk unless there are no other treatment options available. People at 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 (for example, Marfan syndrome or Ehlers-Danlos syndrome), and the elderly.

In order to minimize risk to patients with no alternative treatment options to fluoroquinolones, health care professionals should consider the following actions:

- Advise all patients taking fluoroquinolones to seek immediate medical treatment for any symptoms associated with aortic aneurysm or dissection.
- Stop fluoroquinolone treatment immediately if a patient reports side effects suggestive of aortic aneurysm or dissection.
- Report side effects involving fluoroquinolones or other medications to the FDA MedWatch program.

The FDA has previously communicated the following safety information associated with fluoroquinolones:

- [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
- [July 2008](#) – tendinitis and tendon rupture

To read the full safety announcement, which includes a summary of findings from epidemiological studies and cases from the FDA Adverse Event Reporting System (FAERS) database, refer to the “FDA Drug Safety Communication: FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients” article found on the [Drug Safety and Availability](#) page of the FDA website.