

July 31, 2018



Drug Safety Communication: Adverse Effects from Fluoroquinolone Antibiotics

Fluoroquinolone antibiotics are approved to treat certain serious bacterial infections and work by killing or stopping the growth of bacteria that can cause illness.

On July 10, 2018, the U.S. Food and Drug Administration (FDA) announced it is strengthening the current warnings in the prescribing information for fluoroquinolone antibiotics. The new label changes will add that low blood sugar levels, also called hypoglycemia, can lead to coma, and the new label will also make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class.

The mental health side effects to be added to or updated across all the fluoroquinolones are:

- Disturbances in attention
- Disorientation
- Agitation
- Nervousness
- Memory impairment
- Serious disturbances in mental abilities called delirium

Health care professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin. In order to minimize risk to these patients, health care professionals should consider the following actions:

- Alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients, and discuss with them how to treat themselves if they have symptoms of hypoglycemia.
- Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose.
- Stop fluoroquinolone treatment immediately if a patient reports any central nervous system side effects, including psychiatric adverse reactions or blood glucose disturbances, and switch to a non-fluoroquinolone antibiotic, if possible.
- Stop fluoroquinolone treatment immediately if a patient reports serious side effects involving the tendons, muscles, joints, or nerves, and switch to a non-fluoroquinolone antibiotic to complete the patient's treatment course.

In addition, health care professionals should continue to not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections, because the risks outweigh the benefits in these patients.

To read the full safety announcement, which includes a list of FDA-approved fluoroquinolones, refer to the "FDA Drug Safety Communication: FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes" article found on the [Drug Safety and Availability](#) page of the FDA website.