



FDA MedWatch

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Fluoroquinolone Antibiotics: FDA Requires Labeling Changes Due to Low Blood Sugar Levels and Mental Health Side Effects

ISSUE: FDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects.

BACKGROUND: Fluoroquinolone antibiotics are approved to treat certain serious bacterial infections, and have been used for more than 30 years. They work by killing or stopping the growth of bacteria that can cause illness. Without treatment, some infections can spread and lead to serious health problems.

Most fluoroquinolone antibiotic drug labels include a warning that blood sugar disturbances, including high blood sugar and low blood sugar and depending on the fluoroquinolone antibiotic class, a range of mental health side effects are already described under Central Nervous System Effects in the Warnings and Precautions section of the drug label, which differed by individual drug.

RECOMMENDATION: 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.

FDA continues to monitor and evaluate the safety and effectiveness of medicines after we approve them and they go on the market. In the case of fluoroquinolones, we reviewed reports of cases submitted to FDA and the published medical literature of apparently healthy patients who experienced serious changes in mood, behavior, and blood sugar levels while being treated with systemic fluoroquinolones.

Patients should tell your health care professionals if you are taking a diabetes medicine when your health care professional is considering prescribing an antibiotic, and also if you have low blood sugar or symptoms of it while taking a fluoroquinolone. For patients with diabetes, your health care professional may ask you to check your blood sugar more often while taking a fluoroquinolone. Early signs and symptoms of low blood sugar include:

- confusion
- pounding heart or very fast pulse
- dizziness
- pale skin
- feeling shaky
- sweating
- unusual hunger
- trembling
- headaches
- weakness
- irritability
- unusual anxiety

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.

- 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.

Health care professionals should 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.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online: www.medwatch.gov
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1.800.FDA.0178