Generic Name:
Fluoroquinolone antibiotics
Trade Name:
Multiple trade names
Company:
Multiple companies
Notes:

FDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood glucose and certain mental health adverse effects. The low blood glucose levels can result in serious problems, including coma, particularly in older people and patients with diabetes who are taking medications to reduce blood glucose levels.

The agency announced it is making these changes because a recent review found reports of life-threatening low blood glucose adverse effects and reports of additional mental health adverse effects.

FDA is requiring these updates in the drug labels and to the patient Medication Guides for the entire class of fluoroquinolones (see List of FDA-Approved Fluoroquinolones for Systemic Use). This affects only the fluoroquinolone formulations taken by mouth or given by injection. Blood glucose disturbances, including high blood and low blood glucose levels, are already included as a warning in most fluoroquinolone drug labels; however, FDA is adding that low blood glucose levels (hypoglycemia) can lead to coma.

Across the fluoroquinolone antibiotic class, a range of mental health adverse effects are already described under Central Nervous System Effects in the Warnings and Precautions section of the drug label, which differed by individual drug. The new label changes will make the mental health adverse effects more prominent and more consistent across the systemic fluoroquinolone drug class.

The mental health adverse effects to be added to or updated across all the fluoroquinolones are disturbances in attention, disorientation, agitation, nervousness, memory impairment, and serious disturbances in mental abilities (delirium).

Patients should tell their health professionals if they are taking a diabetes medicine when their health professional is considering prescribing an antibiotic, and also if they have low blood glucose or symptoms of it while taking a fluoroquinolone. Health professionals may ask patients with diabetes to check their blood glucose levels more often while taking a fluoroquinolone.

Health professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in older adults and those with diabetes taking an oral hypoglycemic medicine or insulin. Alert patients of the symptoms of hypoglycemia, 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 adverse effects, including psychiatric adverse reactions, or blood glucose disturbances ,and switch to a nonfluoroquinolone antibiotic if possible. Stop fluoroquinolone treatment immediately if a patient reports serious adverse effects involving the tendons, muscles, joints, or nerves, and switch to a nonfluoroquinolone antibiotic to complete the patient?s treatment course.

Health professionals should not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (uUTI) because the risks outweigh the benefits in these patients.

Medication Monitor Categories:

Alerts and Recalls
