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IN BRIEF

More Fluoroquinolone Warnings

The FDA has required changes in the labeling of all systemic fluoroquinolone antibiotics to strengthen warnings about the risk of severe hypoglycemia and mental health effects associated with their use.¹

An FDA review identified 67 cases of hypoglycemic coma associated with fluoroquinolone use, 22 of which resulted in death or disability. Most cases occurred in patients with risk factors such as diabetes (especially those taking a sulfonylurea), older age, or renal insufficiency.¹ In observational studies in older adults and patients with diabetes, fluoroquinolones have been associated with increased risks of hypo- and hyperglycemia.^{2,3} Patients taking a fluoroquinolone (especially those with risk factors) should be counseled about the symptoms of hypoglycemia and monitored for blood glucose disturbances. The drug should be stopped if dysglycemia occurs.

The labels of all systemic fluoroquinolones will now include warnings about delirium, agitation, nervousness, and disturbances in attention, memory, and orientation. These effects can occur after a single fluoroquinolone dose; the drug should be stopped if such effects occur. Systemic fluoroquinolones can also cause persistent or permanent peripheral neuropathy,⁴ and their use has been associated with an increased risk of pseudotumor cerebri syndrome.⁵

Other serious adverse effects associated with use of systemic fluoroquinolones include tendinitis and tendon rupture, exacerbation of myasthenia gravis, *Clostridium difficile* infection, and (except for delafloxacin [*Baxdela*]) QT-interval prolongation and torsades de pointes. The FDA recommends avoiding use of fluoroquinolones in patients with uncomplicated urinary tract infection, acute sinusitis, or acute exacerbation of chronic bronchitis, except when no alternative treatment option is available.⁶ ■

Additional Content Available Online

Comparison Table: Some Systemic Fluoroquinolones
<http://medicalletter.org/TML-article-1543f>

1. FDA. July 10, 2018. Available at: www.fda.gov/Drugs/DrugSafety/ucm611032.htm. Accessed August 2, 2018.
2. LY Park-Wyllie et al. Outpatient gatifloxacin therapy and dysglycemia in older adults. *N Engl J Med* 2006; 354:1352.
3. HW Chou et al. Risk of severe dysglycemia among diabetic patients receiving levofloxacin, ciprofloxacin, or moxifloxacin in Taiwan. *Clin Infect Dis* 2013; 57:971.
4. In brief: Fluoroquinolones and peripheral neuropathy. *Med Lett Drugs Ther* 2013; 55:89.
5. M Sodhi et al. Oral fluoroquinolones and risk of secondary pseudotumor cerebri syndrome: nested case-control study. *Neurology* 2017; 89:792.
6. Alternatives to fluoroquinolones. *Med Lett Drugs Ther* 2016; 58:75.

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