Stronger Warnings Requested for Fluoroquinolones

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The Food and Drug Administration (FDA) has notified manufacturers of fluoroquinolone antimicrobial drugs that a boxed warning on the increased risk of tendinitis and tendon rupture is necessary. A boxed warning on a drug's label calls attention to serious or life-threatening risks.

The agency has also determined that manufacturers should provide patients with a Medication Guide about possible side effects. Medication Guides are paper handouts that come with certain prescription medications.

What are fluoroquinolones?

Fluoroquinolones are drugs approved for the treatment or prevention of certain bacterial infections. Like other antibacterial drugs, fluoroquinolones do not treat viral infections such as colds or flu.

Which drugs are involved in this action?

These warnings would apply to fluoroquinolones for systemic use (e.g., pills, tablets, capsules and injectable formulations). The warnings would not apply to fluoroquinolones for topical ophthalmic or otic use (e.g., eye and ear drops).

The medications involved in this action are: Cipro and generic ciprofloxacin, Cipro XR and Proquin XR (ciprofloxacin extended release), Factive (gemifloxacin), Levaquin (levofloxacin), Avelox (moxifloxacin), Noroxin (norfloxacin), and Floxin and generic ofloxacin.

What should patients know?

The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in people older than 60, in people taking corticosteroid drugs, and in kidney, heart, and lung transplant recipients.

- Patients experiencing pain, swelling, inflammation of a tendon or tendon rupture should stop taking their fluoroquinolone medication and contact their health care professional promptly about changing their antimicrobial therapy.
- Patients should also avoid exercising and using the affected area at the first sign of tendon pain, swelling, or inflammation.

This article appears on FDA's Consumer Updates page, which features the latest on all FDA-regulated products.

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