Agency Issues 'Black Box' Warning for Antibiotics Known as Fluroquinolones
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July 8, 2008 — Federal regulators are ordering new warnings on Cipro and similar antibiotics because of increased risk of tendinitis and tendon rupture. The new warnings apply to fluoroquinolones, a class of antibiotics that includes the popular drug Cipro. The FDA has told companies that the drugs must now carry "black box" warnings alerting doctors and patients that the drugs can increase risk of tendinitis and tendon rupture in some patients. Fluoroquinolones have carried similar warnings for years, but officials say they continue to receive reports of safety problems. A "black box" warning is the FDA's sternest warning.

"We have seen continuing reports of tendon rupture so we are trying to increase awareness," says Edward Cox, MD, director of the FDA's Office of Antimicrobial Products.

The warning applies to drugs of the fluoroquinolone class, including Cipro, Cipro XR, Proquin XR, Levaquin, Floxin, Noroxin, Avelox, Factive, and marketed generics.

Renata Albrecht, MD, who heads the FDA's Division of Special Pathogen and Transplant Products, estimates that spontaneous ruptures occur in about one in 100,000 people. The agency says taking the drugs appears to triple or quadruple the risk.

Most of the tendinitis and tendon ruptures affect the Achilles tendon, behind the ankle. But the agency has also received reports of tendinitis and ruptures in the shoulder and hand. Tendons connect muscle to bone.

Officials also say they are adding new warnings cautioning that patients over 60, those taking corticosteroids, and those who've undergone heart, lung, or kidney transplants are also at increased risk of tendon rupture or tendinitis if they take fluoroquinolones.

Researchers don't know exactly what fluoroquinolones do that promotes tendon rupturing. Theories suggest the drug may impede collagen formation or interrupt blood supply in joints, Albrecht says.

She says patients taking the drugs should tell their doctors immediately if they experience soreness or inflammation in muscles or tendons and that they should not exercise affected joints.

A consumer watchdog group sued the FDA in January asking for the new warnings. The agency has received more than 400 reports of tendon ruptures in fluoroquinolone patients since 1997, according to Public Citizen's Health Research Group, which filed the suit.

FDA officials would not confirm the number of reports of ruptures it has received, citing the ongoing litigation.

“There are several hundred, I would say,” says Ann McMahon, MD, acting director of FDA’s Division of Adverse Event Analysis II