The Truth About Health

FDA to Require Box Warning For Cipro ® and Similar Antibiotics

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It's taken over 12 years since an original petition was filed, but the US Food and Drug Administration (FDA) is finally getting around to putting a Black Box Warning label on the antibiotic Cipro and other similar antibiotics.

Back in 1996, the watchdog group Public Citizen initially presented evidence to the FDA in the form of a petition to require stronger warning labels for all drugs containing fluoroquinolone antibiotics due to reported increased risks of patients developing tendonitis or experiencing tendon rupture. These types of antibiotics are widely prescribed for gastrointestinal, respiratory and urinary infections. The FDA honored the 1996 petition, but warnings about the product were buried in a list of possible reactions and considered inadequate.

Public Citizen reviewed the FDA's adverse events database form 1997 to 2005 and found enough evidence of tendon problems to submit another warning petition in 2005. During this period of time, there were 262 cases of tendon ruptures reported and over 500 cases of tendonitis and other tendon disorders. Ruptures of the Achilles tendon were the most sudden and severe. Other areas of the body affected include the rotator cuff, the biceps, the hand and the thumb. (Tendons are tough fibrous tissue that connects muscles to joints.)

The reason that fluoroquinolone drugs affect the tendons in this manner is not completely known. One theory is that these antibiotics are toxic to tendon fibers and may cause a decrease in the blood supply to tendons, a part of the body that already operates on a limited blood supply.

The recent FDA action to raise the status of Cipro to a Black Box Warning is the result of a suit filed against the FDA by Public Citizen for failing to honor petition requests from over 2 years ago. The FDA will now issue a notice to all manufacturers of fluoroquinolone drugs to add a boxed warning regarding the likelihood of developing tendonitis or experiencing tendon rupture. Manufacturers will also be directed to develop a "medication guide" for patients.

Persons who are taking Cipro or other fluoroquinolone drugs should be instructed to stop taking them immediately if they develop tendon pain. Symptoms may include swelling, inflammation and tears of a tendon. Persons who are over 60 years of age are considered to be at higher risk of tendon-related problems. Also in the higher risk category is anyone taking steroids, as well as persons who have had organ transplants, according to the FDA.

The following list of medications are being targeted by the FDA for Black Box Warnings: Cipro, CiproXR ®, ProquinXR ®, Factive ®, Levaquin ®, Avelox ®, Noroxin ® and generic ofloxacin, also marketed as Floxin ®.

Source: The US Federal Drug Administration. "Information for Health Care Professionals." July 2008.

http://www.fda.gov/cder/drug/InfoSheets/HCP/fluoroquinolonesHCP.htm and Public Citizen. “FDA Should Warn of Tendon Ruptures Linked to Cipro, Levaquin, Other Antibiotics in Same Class.” Press Release. August 2006. http://www.tradewatch.org/pressroom/release.cfm?ID=2262