Fluoroquinolones

EAlerts
- Azithromycin and levofloxacin may increase the risk of cardiovascular death
- FDA should stop ignoring risk of tendon rupture from antibiotic

Disease and Drug Family Information
- Antibiotics [hide all summaries]
  Antibiotics (drugs used to treat bacterial infections) are overwhelmingly misprescribed in the United States. Despite congressional hearings and numerous academic studies on this issue, it has become the general consensus that 40 to 60% of all antibiotics in this country are misprescribed. New studies continue to confirm the fact that a large proportion of antibiotic prescribing for both children and adults continues to be inappropriate.
- Fluoroquinolones [hide all summaries]
  One of the biggest-selling and most overprescribed classes of drugs in the United States is the family called fluoroquinolones. One clue that a drug your doctor wants to give you is in this class is the fact that the generic names of all such drugs approved in the United States include the sequence floxacin. These drugs have been alternatives for individuals allergic to, or with infections resistant to, other antibiotics. Some fluoroquinolones are commonly misprescribed for colds, sore throats, bladder infections, or community-acquired (as opposed to hospital-acquired) pneumonia.

Drug and Dietary Supplement Profiles - Each profile is a comprehensive review of the safety and effectiveness of this drug. If drug is not a Do Not Use product, information on adverse effects, drug interactions and how to use the medication are included.
- moxifloxacin [eye drops] (VIGAMOX); ofloxacin [eye] (OCUFLOX)
- gatifloxacin (TEQUIN); moxifloxacin (AVELOX); sparflloxacin (ZAGAM)
- ciprofloxacin (CILOXAN, CIPRO); levofloxacin (LEVAQUIN); lomefloxacin (MAXAQUIN); ofloxacin (FLOXIN)
- norfloxacin (CHIBROXIN, NOROXIN)
- trovaflloxacin (TROVAN)
- gemifloxacin (FACTIVE)

Worst Pills, Best Pills Newsletter Articles
- Increased Risk of Cardiovascular Death With Azithromycin and Levofloxacin [hide all summaries]
  (August 2012)
  We review recent evidence that azithromycin (ZITHROMAX, as in Z-PAK) and levofloxacin (LEVAQUIN), used for relatively short periods, significantly increased the risk of cardiovascular risks such as sudden cardiac death in some patients, compared to the risks in people not taking antibiotics. The overprescribing of these drugs is also discussed.
- **Fluoroquinolone Antibiotics Associated With Increased Risk of Retinal Detachment** [hide all summaries]
  (July 2012)
  Find out the most common symptoms of the vision-threatening condition retinal detachment and how, although rarely, it can be caused by commonly used antibiotics such as ciprofloxacin (CIPRO) and levofloxacin (LEVAQUIN). We also discuss evidence that these antibiotics are overused.

- **Update on Withdrawals of Dangerous Drugs in the U.S.** [hide all summaries]
  (January 2011)
  This article lists 11 of the prescription drugs that we warned Worst Pills, Best Pills News subscribers not to use before they were banned by the FDA. Subscribers knew an average of 3.3 years before the FDA acted that these medications were unsafe to use.

- **The Dangers of Combining Sleeping Pills With Other Medication** [hide all summaries]
  (September 2010)
  The article lists 34 other medications that can harmfully interact with sleeping pills, increasing their sedative properties and causing excessive sedation. Excessive sedation at night could increase the risk of falls, should the person get up in the night for some reason. Moreover, excessive sedation causing respiratory depression could be dangerous for people with certain disorders, such as lung disease.

- **Smoke & Mirror Marketing (& Other Clever Big Pharma Tricks)** [hide all summaries]
  (May 2010)
  The article reviews 12 prescription drugs, many of which are top-sellers, all of which are greatly overpriced in comparison to older "versions" of the same drugs. The patents on the old drugs expired so the "innovative" companies patented these new products, gaining a patent on them, and, for all practical purposes, using them as a license to print money. There is no evidence that any of the new ones are better than the now less-expensive, old versions.

- **Antacid Drug Interactions** [hide all summaries]
  (October 2009)
  Antacids can interact with a number of medications, either increasing or decreasing drug effect.

- **Drug-induced Cognitive Impairment: Part 2; Delirium and Dementia** [hide all summaries]
  (April 2009)
  This second article about drug-induced dementia or delirium lists and discusses an additional 79 drugs that can cause these reversible kinds of mental deterioration. The two articles collectively review 136 drugs that can cause these serious side effects, especially in older people.

- **Tizanidine: Watch Out for Drugs Interacting With This Muscle Relaxant** [hide all summaries]
  (October 2008)
  Tizanidine (ZANAFLEX) is a muscle relaxant for which more than 3.8 million prescriptions were filled in the U.S. last year. The article lists more than 64 drugs with which it can have dangerous interactions resulting in excess sedation, difficulty breathing or dangerously low blood pressure that can result in falling.

- **FDA Must Warn Patients Taking Fluoroquinolone Antibiotics of Possible Tendon**
Ruptures [hide all summaries]  
(October 2008)

After a petition and lawsuit by Public Citizen's Health Research Group, the FDA announced in July that it will require a “black box” warning concerning tendon rupture and tendinitis caused by fluoroquinolone antibiotics, as well as an FDA-approved medication guide to be dispensed when prescriptions are filled. Although this accomplishes two of the three steps Public Citizen has urged the agency to take for nearly two years, we are troubled that the FDA is not doing everything within its power to prevent more people from needlessly suffering disabling tendon ruptures. Nothing could be simpler and more effective than a letter to doctors in addition to what the FDA has already agreed to do.

- 29 Medications That May Cause Adverse Interactions with Thyroid Drugs [hide all summaries]  
(September 2008)

Thyroid medications are among the most widely-prescribed drugs in the U.S. In this article, we review 29 different medications that can have harmful interactions with thyroid medicines such as levothyroxine (Synthroid). There are four major kinds of interaction problems that can occur: • Certain medications can decrease the absorption of levothyroxine resulting in lower levels in the blood. • Other medications can increase the rate at which the body gets rid of levothyroxine, also resulting in lower thyroid levels in the blood. • Other medications can cause changes of levothyroxine binding in blood, decreasing the body's ability to use levothyroxine. • Levothyroxine can affect the safety or effectiveness of other medications by raising or lowering the levels of these other drugs in the blood, causing them to be either infective (lower levels) or dangerous (higher levels).

- FDA Issues New Warnings For Muscle Spasm Drug Tizanidine (ZANAFLEX) [hide all summaries]  
(August 2007)

The muscle spasm drug tizanidine (ZANAFLEX) combined with certain other drugs could cause serious complications such as drowsiness and can dramatically lower blood pressure, according to the Food and Drug Administration (FDA). The article lists 20 drugs to avoid if you are using Zanaflex so that you avoid these potentially dangerous interactions.

- Public Citizen Urges FDA to Warn Consumers About Risk of Tendon Rupture Associated With Certain Antibiotics [hide all summaries]  
(November 2006)

You should stop taking fluoroquinolones(listed in the article) and immediately contact your physician if you experience pain in any tendon while taking one of these antibiotics so you can be switched to another antibiotic.

- Fluoroquinolone Antibiotics Implicated in Life-Threatening Diarrhea [hide all summaries]  
(February 2006)

Antibiotic-associated diarrhea (AAD) is quite common and its incidence varies from 5% to 20% of patients depending on which antibiotic they are taking. The article lists some of the drugs most associated with this potentially life-threatening adverse reaction.

- Serious Blood Sugar Reactions With the Fluoroquinolone Antibiotic Gatifloxacin
(TEQUIN)  [hide all summaries]  
(February 2006)  
On Dec. 21, 2005, the Canadian equivalent of the Food and Drug Administration (FDA), Health Canada, warned the public and healthcare professionals of serious cases of both low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia) with the use of the fluoroquinolone antibiotic gatifloxacin (TEQUIN).

- **Drug Induced Peripheral Neuropathy From The Fluoroquinolone Antibiotics**  [hide all summaries]  
(December 2004)  
The Food and Drug Administration (FDA) now requires that the professional product labeling, or package inserts, for all fluoroquinolone antibiotics must warn about the possibility of peripheral neuropathy (nerve damage). A list of the fluoroquinolone antibiotics currently available in the U.S. appears at the end of this article.

- **Drug Interaction Reminder: Fluoroquinolone Antibiotics and the Anticoagulant (Blood Thinner) Warfarin (COUMADIN)**  [hide all summaries]  
(September 2004)  
You should consider that all fluoroquinolone antibiotics have the potential to interact with warfarin and your physician should be ordering blood tests to monitor the status of your blood clotting if one of these antibiotics is needed and you are using warfarin. This is the safest thing to do.

- **Drug-Induced Taste Disorders**  [hide all summaries]  
(September 2003)  
DO NOT stop taking any of the drugs listed in the table without first consulting your physician. You should report any alteration in your sense of taste to your physician if you are taking a drug.

- **Inappropriate Prescribing Of Fluoroquinolone Antibiotics, Ciprofloxacin (CIPRO), Gatifloxacin (TEQUIN), And Others**  [hide all summaries]  
(July 2003)  
In this study, the researchers evaluated 100 consecutive patients who went to the emergency room and received a prescription for a fluoroquinolone antibiotic. Of the 100 patients, 81 (81%) received a fluoroquinolone antibiotic for an inappropriate use. In 43 (53%) of these patients, a fluoroquinolone was found inappropriate because another antibiotic was considered first-line treatment, and in 27 (33%) patients there was no evidence of an infection and therefore no indication for the use of any antibiotic.

- **Stronger Warnings for the Fluoroquinolone Antibiotic Gatifloxacin (TEQUIN)**  [hide all summaries]  
(May 2003)  
Stronger warnings have been added to the professional product label, or “package insert,” for the fluoroquinolone antibiotic gatifloxacin (TEQUIN) about possible heart rhythm disturbances and problems with blood sugar control. This drug was approved by the Food and Drug Administration (FDA) in October 2001 and its marketing brought to nine the number of fluoroquinolone antibiotics on the market.

- **Selling New Drugs Using Smoke and Mirror (Images)**  [hide all summaries]  
(March 2003)  
You should avoid these "new" single mirror images of old drugs, not out of concern about their safety or effectiveness, but because they are the same as the old drugs. In the
long run, they cause economic harm both to individuals and to the health care system because they have come on the market with extended monopoly protection. Article lists some examples.

- **Drug Induced Psychiatric Symptoms** [hide all summaries]
  (October 2002)
  This is the first of a two part series on drug induced psychiatric symptoms that is based on the July 8, 2002 issue of The Medical Letter on Drugs and Therapeutics. Regular readers of Worst Pills, Best Pills News will recognize The Medical Letter as a reference source written for physicians and pharmacists that we often use because of its reputation as an objective and independent source of drug information. The article lists the drugs and their psychiatric adverse effects.

- **Do Not Use! The Fluoroquinolone Antibiotic Gatifloxacin (TEQUIN)** [hide all summaries]
  (July 2002)
  The approval of gatifloxacin(TEQUIN) in October 2001 brought to nine the number of fluoroquinolone antibiotics on the market, and this drug joins sparfl oxacin (ZAGAM) and moxifloxacin (AVELOX) as fluoroquinolones that can cause a dangerous abnormality in the heart’s electrical conduction known as QT prolongation that can lead to fatal heart rhythm disturbances such as torsade de pointes.

- **Drugs for Possible Exposure to Anthrax: What Makes Sense?** [hide all summaries]
  (November 2001)
  With each new day come new reports of exposures, possible exposures and what turn out to be fake exposures to anthrax. Originally coming from Florida, reports are now emanating from other states including New York, Nevada and the District of Columbia.

Additional Information from Public Citizen

- **FDA Must Do More to Warn Patients Taking Fluoroquinolone Antibiotics of Possible Tendon Ruptures** [hide all summaries]
  Statement of Sidney Wolfe, M.D., Director of the Health Research Group at Public Citizen

- **Antibiotic Leads to Tendon Ruptures; FDA Ignores Risks** [hide all summaries]
  Despite long-standing evidence that fluoroquinolone antibiotics can cause tendon ruptures, the Food and Drug Administration (FDA) has failed to increase its warnings to patients and physicians about the dangers of the medicines, Public Citizen told a federal court Thursday.

- **Public Citizen Petitions the FDA to Include a Black Box Warning on Fluoroquinolone Antibiotics (HRG Publication #1781)** [hide all summaries]
  Public Citizen, representing more than 100,000 consumers nationwide, hereby petitions the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug and Cosmetic Act 21 U.S.C. Section 355(e)(3), and 21 C.F.R. 10.30, to immediately add a black box warning regarding the risks of tendinopathy and tendon rupture to the product labels of all fluoroquinolone antibiotics presently on the market in the United States.

- **Petition to the FDA to Immediately Ban the Antibiotic Gatifloxacin (Tequin) (HRG Publication #1768)** [hide all summaries]
  Petition to the FDA to Immediately Ban the Antibiotic Gatifloxacin (Tequin) (HRG Publication #1768)
• **Letter to the Editor of the New York Times concerning mis-statements by HHS Secretary Tommy Thompson on drugs used to treat anthrax (HRG Publication #1598)** [hide all summaries]
  You quote Tommy G. Thompson, the secretary of Health and Human Services, as saying doxycycline and penicillin are just as effective as Cipro (news article, Oct. 20). The major study in the field, published by United States Army researchers in 1993, does not support this statement.

• **Letter to the Department of Health and Human Services urging that they implement and enforce the Code of Ethics for Government (HRG Publication #1516)** [hide all summaries]
  It is urgent for you and other leaders in HHS--and all government agencies--to re-read and strongly urge the implementation and enforcement of a 1958 Congressional Resolution entitled The Code of Ethics for Government Service (175 72 Stat B12, 1958) which states that "Any person in Government Service should put loyalty to the highest moral principles and to country above loyalty to persons, party or Government department."

• **Letter to the Editor in the Journal of the American Medical Association in response to an article on the safety of Food and Drug Administration approved drugs which were withdrawn (HRG Publication #1502)** [hide all summaries]
  Letters-Science by Peter Lurie, M.D., M.P.H. Larry Sasich, Pharm.D., M.P.H. Letter to the Editor in the Journal of the American Medical Association in response to an article on the safety of Food and Drug Administration approved drugs which were withdrawn

• **Letter to the Food and Drug Administration to immediately ban the antibiotic trovafl oxacin (Trovan) (HRG Publication #1485)** [hide all summaries]
  we hereby petition the Food and Drug Administration (FDA) as authorized by 21 U.S.C. , section 355 (e) of the Federal Food, Drug and Cosmetic Act to immediately ban the widely-used antibiotic, TROVAN (trovafl oxacin, Pfizer), before more patients die, require a liver transplant or are otherwise injured from liver toxicity caused by this drug.

• **Petition to Require a Warning on All Fluoroquinolone Antibiotics (HRG Publication #1399)** [hide all summaries]
  Based on more than 130 reports of tendon inflammation (many involving rupture), most frequently involving the Achilles tendon, in persons using the widely-prescribed class of antibiotics known as fluoroquinolones, Public Citizen, representing consumers nationwide, hereby petitions the F.D.A. to add a warning about this serous problem to the label of all fluoroquinolone antibiotics marketed in the United States. These include: *Health Letter Articles*

• **Outrage: New Study: Wait Seven Years to Use New Drugs** [hide all summaries] (June 2002)
  A study published in the May 1, 2002 Journal of the American Medical Association (JAMA) has resulted in a major change in the Health Research Group's drug safety policy. The study, in association with physicians from the Harvard Medical School, examined the frequency and timing of the identification of new adverse drug reactions resulting in the addition of a black box warning in the drug's professional product labeling or its outright removal from the market. Three of the authors have close
identification with the Health Research Group: its director, Sidney M. Wolfe, and former HRG staffers Drs. Steffi Woolhandler and David Himmelstein. The other co-authors are affiliated with the Harvard Medical School.