

“...To reduce the development of drug-resistant bacteria and maintain the effectiveness of LEVAQUIN® and other antibacterial drugs, LEVAQUIN® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria [1]...” Whenever possible alternative drugs with fewer side-effects are adequate to treat these types of infections.”..FDA Flyer – see link below

The side effects from taking these drugs are listed in U.S. FDA Reports on Bioterrorism Drugs [1], by the Mayo Clinic [3] and by other government sources [4].

BIOTERRORISM DRUGS – Fluoroquinolones:

READ THE FINE PRINT!

LEVAQUIN, CIPRO and many others on list below

Doctors are prescribing a number of U.S. Food & Drug Administration (FDA), Emergency Preparedness Bioterrorism Drugs for a variety of symptoms in hospitals and in their offices locally and across the United States. Many times inadequate warnings are given their patients of the short and long term side-effects or the availability of other prescription drugs with less toxic side-effects that could be used.

The following information from the U.S. FDA gives the Brand Name listings of some of the Fluoroquinolone bioterrorism drugs which are now being prescribed by doctors [2]:

“...Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drug Listing:

- *Ciprofloxacin (marketed as Cipro and generic Ciprofloxacin);
- *Ciprofloxacin Extended-Release (marketed as Cipro XR and Proquin XR),
- *Gemifloxacin (marketed as Factive),
- *Levofloxacin (marketed as Levaquin),
- *Moxifloxacin (marketed as Avelox),
- *Norfloxacin (marketed as Noroxin), and
- *Ofloxacin (marketed as Floxin) [2]

The side effects from taking these drugs are listed in U.S. FDA Reports on Bioterrorism Drugs [1], by the Mayo Clinic [3] and by other government sources [4]. These sources

list multiple side-effects which you may experience long after taking the drug and these side-effects may be permanent, recur without warning, or be intermittent in nature.

In many instances patients admitted to hospitals are not warned in advance that one of these drugs may be used to treat their symptoms. Hospital consultations on use of bioterrorism and other drugs should take place prior to being used on patients, including notification about effective drugs with less serious side-effects. This would give patients and family members a choice of possible alternatives and also prevent the use of drug which could impair their health in the future.

One class of drugs which is currently being prescribed in increasing numbers to patients are U.S. Food & Drug Administration Bioterrorism Drugs like Fluoroquinolones. These drugs have many side-effects which can appear days, weeks, or months after discontinuing usage [1]: "...WARNING: Fluoroquinolones, including LEVAQUIN[®], are associated with an increased risk of tendinitis and tendon rupture in all ages. **This risk is further increased in older patients usually over 60 years** of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants..."

One such drug may be prescribed for the following symptoms [1] "...LEVAQUIN[®] is a fluoroquinolone antibacterial...infections caused by designated, susceptible bacteria:

Pneumonia: nosocomial and community acquired

Acute bacterial sinusitis

Acute bacterial exacerbation of chronic bronchitis

Skin and skin structure infections: complicated and uncomplicated

Chronic bacterial prostatitis

Urinary tract infections: complicated and uncomplicated

Acute pyelonephritis

Inhalational anthrax, post-exposure. Not tested in humans for post-exposure prevention of inhalational anthrax; plasma concentrations are likely to predict efficacy..." [1].

A U.S. FDA ALERT on July 8, 2008 [2]: "FDA is notifying the makers of fluoroquinolone antimicrobial drugs for systemic use of the need to add a boxed warning to the prescribing information about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones..." Many lawsuits can be found online with regard to fluoroquinolone side-effects.

The U.S. FDA Alert also gives the following information: “...serious adverse reactions which may include convulsions, hallucinations, depression...diarrhea. Rarely, damage to the liver, kidneys or bone marrow, or alterations in glucose homeostasis may occur...” [2]

In addition, other side-effects which have been noted in government reports [1] and on product labels, include, but are not limited to: “...Central nervous system effects, including convulsions, anxiety, confusion, depression, and insomnia may occur after the first dose. Use with caution in patients with known or suspected disorders that may predispose them to seizures or lower the seizure threshold... Peripheral neuropathy: discontinue if symptoms occur in order to prevent irreversibility...risks increase in persons over 60...” For a complete listing of these symptoms the U.S. FDA Report has 65 pages of information on this type of drug [1].

1, U.S. Food & Drug Administration Information on this Bioterrorism Drug – This is a 65 Page document on Levofloxacin- Brand Name: Levaquin
<http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM133684.pdf>

Other reported symptoms, nausea, diarrhea, headache, dizziness, lightheadedness, trouble sleeping, long term health effects or new yeast infections, fever, sore throat, and symptoms that may be reversible if identified and treated early. Other symptoms include chest pain, vision changes, shaking, seizures, fainting, nervousness, confusion, hallucinations, depression, rare thoughts of suicide, liver problems, stomach pain, unusual tiredness, rash, swelling, intestinal conditions, blood pressure changes which include fast irregular heartbeat, and if you are taking other drugs to regulate the heartbeat; the list is a long one.

Some of these conditions may return “weeks or months after treatment” when the previous use of these types of drugs has been long forgotten by the patient and their doctors. The wrong treatment without knowing the drug related cause can make these conditions worse. Laboratory tests should be performed periodically to check for side-effects.

Well-educated pharmacists across the United States work at pharmacies which provide to the public medications prescribed by doctors. They are your first line of defense in learning about the drugs you are taking, the symptoms from taking those drugs, and any interactions from taking multiple prescription and over the counter drugs. They provide warnings, will evaluate all prescriptions being taken, and provide information on side-effects.

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to be caused by susceptible bacteria [1]...” Whenever possible alternative drugs with fewer side-effects are adequate to treat these types of infections.

All of this information is available to you from your local pharmacist, online, and from government reports. Protect yourself and your family by investigating the symptoms of these drugs before taking and require hospitals to inform you before they use this drug on you while you are in the hospital without your knowledge.

Respectfully,

Rosalind Peterson
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1, U.S. Food & Drug Administration Information on this Bioterrorism Drug – This is a 65 Page Document on Levofloxacin- Brand Name: Levaquin

<http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM133684.pdf>

3, <http://www.mayoclinic.com/health/drug-information/DR600845>

<http://www.mayoclinic.com/health/drug-information/DR600845/DSECTION=precautions->

<http://www.mayoclinic.com/health/drug-information/DR600845/DSECTION=side-effects>

<http://www.mayoclinic.com/health/drug-information/DR600845/DSECTION=side-effects>

4, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001011/>

<http://www.rxlist.com/levaquin-drug.htm>

<http://www.rxlist.com/levaquin-drug/patient-images-side-effects.htm>

<http://www.rxlist.com/levaquin-drug/patient-images-side-effects.htm>

2, **United States Food & Drug Administration Information:**

<http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm126085.htm>

“...Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs [ciprofloxacin (marketed as Cipro and generic ciprofloxacin), ciprofloxacin extended-release (marketed as Cipro XR and Proquin XR), gemifloxacin (marketed as Factive), levofloxacin (marketed as Levaquin), moxifloxacin (marketed as Avelox), norfloxacin (marketed as Noroxin), and ofloxacin (marketed as Floxin)]”

FDA ALERT [7/8/2008]: FDA is notifying the makers of fluoroquinolone antimicrobial drugs for systemic use of the need to add a boxed warning to the prescribing information about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones and to develop a Medication Guide for patients. The addition of a boxed warning and a Medication Guide would strengthen the existing warning information already included in the prescribing information for fluoroquinolone drugs.

Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their doctor about changing to a non-fluoroquinolone antimicrobial drug.

Selection of a fluoroquinolone for the treatment or prevention of an infection should be limited to those conditions that are proven or strongly suspected to be caused by bacteria.

This information reflects FDA's current analysis of data available to FDA concerning fluoroquinolone antimicrobials. FDA intends to update this sheet when additional information or analyses become available.

Adverse reactions or quality problems experienced with the use of this Product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, using the contact information at the bottom of this sheet.

FDA is notifying the makers of fluoroquinolone antimicrobial drugs of the need to add a *Boxed Warning* to the prescribing information about the increased risk of tendinitis and tendon rupture in patients taking fluoroquinolones and to develop a Medication Guide for patients.* Fluoroquinolone antimicrobial drugs are used to treat various bacterial infections. Marketed fluoroquinolone antimicrobial drugs include ciprofloxacin (marketed as Cipro and generic ciprofloxacin), ciprofloxacin extended release (Cipro XR and Proquin XR), gemifloxacin (marketed as Factive), levofloxacin (marketed as Levaquin), moxifloxacin (marketed as Avelox), norfloxacin (marketed as Noroxin), and ofloxacin (marketed as Floxin and generic ofloxacin).

The information regarding warnings for fluoroquinolones and adverse effects on tendons applies to fluoroquinolones for systemic use (e.g., tablets, capsules and injectable formulations); it does not apply to fluoroquinolones for ophthalmic or otic use (e.g., eye drops and ear drops).

Recommendations and Information for Healthcare Professionals to Consider Regarding Fluoroquinolones:

- **Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture.** This risk is further increased in those over age 60, those on concomitant steroid therapy, as well as in kidney, heart, and lung transplant recipients. The fluoroquinolone should be discontinued if the patient experiences pain or inflammation in a tendon (symptoms that may precede rupture of the tendon), or tendon rupture. Advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their healthcare provider about changing to a non-fluoroquinolone antimicrobial drug.
- **Healthcare professionals should consider the potential benefit and risks to each individual patient before prescribing a fluoroquinolone antimicrobial.** While most patients prescribed fluoroquinolones tolerate these medicines, rarely patients develop serious adverse reactions which may include convulsions, hallucinations, depression, QTc prolongation and torsade de pointes, or *Clostridium difficile* associated diarrhea. Rarely, damage to the liver, kidneys or bone marrow, or alterations in glucose homeostasis may occur.
- **Fluoroquinolones should only be used for the treatment or prevention of infections that are proven or strongly suspected to be caused by bacteria.** Fluoroquinolones, like other antibacterial drugs, do not treat viral infections such as the common cold or influenza.

Information for Healthcare Professionals to Provide When Counseling Patients:

- **Tendon rupture**
- Pain, swelling, inflammation, and tears of tendons including the Achilles, shoulder, hand, or other tendons can happen in patients taking fluoroquinolone antibiotics. Tendons are the areas that connect your muscles to your joints. The Achilles tendon is at the back of the ankle.
The chance of getting tendon problems is higher if you are:
 - **over 60 years of age**
 - **taking steroids (corticosteroids)**
 - **a kidney, heart, or lung transplant recipient**

- Other reasons for tendon ruptures include:
 - physical activity or exercise
 - kidney failure
 - tendon problems in the past, such as with rheumatoid arthritis

- Call your healthcare provider right away at the first signs or symptoms of pain, swelling or inflammation in a tendon area. These could be symptoms of tendinitis or tendon rupture. Stop taking your fluoroquinolone until a healthcare provider has determined that you do not have tendinitis or a tendon rupture.

Signs or symptoms of tendon rupture include:

 - a snap or pop in a tendon area
 - bruising right after an injury in a tendon area
 - inability to move the affected area or bear weight

- At the first sign of pain, swelling, or inflammation in a tendon area, avoid exercise and use of the affected area.
- Talk to your healthcare provider about the risk of tendon rupture with continued use of a fluoroquinolone and whether you should be prescribed a different type of antibiotic to treat your infection.

- Tell your doctor about other medicines that you take and other medical conditions that you have. Some medicines may interact with a fluoroquinolone and cause serious side effects. Also, some medical conditions may make you more likely to have a serious side effect when you take a fluoroquinolone.

- Fluoroquinolones, like any drug, have possible side effects associated with their use. Rarely, some side effects may be serious or even fatal; however, most of the risks are mild. Some of the most serious side effects include seizures, hallucinations, depression, heart rhythm changes (QTc prolongation and torsade de points), and intestine infection with diarrhea. Rarely, damage to the liver, kidneys or bone marrow, and changes to blood sugar may occur.

- Fluoroquinolones are antimicrobials that are effective in treating infections caused by certain bacteria. They do not help to treat infections caused by viruses, such as a common cold or the flu.

Background Information

A warning about the increased risk of tendinitis and tendon rupture in patients taking fluoroquinolones was previously added to the prescribing information for fluoroquinolones. However, FDA's recent evaluation of the medical literature and the post-marketing adverse event reports submitted to the Adverse Events Reporting

System (AERS) confirmed that serious reports of tendinitis and tendon rupture with the fluoroquinolones continue to be reported in similar or increased numbers.

Tendinitis and tendon rupture most frequently involves the Achilles tendon, and rupture of the Achilles tendon may require surgical repair. Tendinitis and tendon rupture in the rotator cuff (the shoulder), the hand, the biceps, and the thumb have also been reported. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is especially increased in patients over 60 years, in those concomitantly taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Tendon rupture can occur during or after completion of fluoroquinolone use; cases occurring up to several months after completion of therapy have been reported.

Tendon rupture is a serious adverse event that could potentially be prevented or reduced in frequency or severity by appropriate use of a fluoroquinolone, patient selection, and careful monitoring. Therefore, FDA is notifying the makers of the fluoroquinolones of the need to add a *Boxed Warning* to the prescribing information for fluoroquinolones to highlight and strengthen the existing warning about the increased risk of fluoroquinolone-associated tendinitis and tendon rupture. FDA is also notifying the makers of fluoroquinolones of the need to develop and distribute a Medication Guide to alert patients about these possible side effects.

*This notification was made under FDA's new authority to require safety labeling changes and risk evaluation and mitigation strategies provided in Title IX of the FDA Amendments Act of 2007 (creating new sections 505(o)(4) and 505-1(a)(2) of the Federal Food, Drug, and Cosmetic Act)..."

Related Information:

- [FDA Public Health Alert: Healthcare Professionals Warned Not To Use Certain Intravenous Metronidazole, Ondansetron, and Ciprofloxacin Due To Potential Contamination¹](#)

<http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismAndDrugPreparedness/UCM130802.pdf>

CIPRO

http://www.medicationsense.com/articles/may_aug_05/warning_antibiotics_052205.html

Just in - dated 9/21/12: Med News :

Ciprofloxacin Use Is Major Contributor To MRSA Spread In Hospitals

<http://www.news-medical.net/news/20120921/Ciprofloxacin-use-is-major-contributor-to-MRSA-spread-in-hospitals.aspx>

EXCERPT: "Dr Lindsay said the study suggested that MRSA relies on ciprofloxacin - and fluoroquinolones in general - to thrive in hospitals, as well as penicillin-type drugs, which was already assumed. The fluoroquinolone group of antibiotics have a similar enough mechanism of action to assume that the effect would be the same for them all.

She added that the findings suggest the most effective way to control MRSA and other hospital-based superbugs is to continue finding alternative ways to use antibiotics, rather than simply focusing on infection control techniques.

As well as identifying factors that influenced prevalence, the researchers identified the strain of MRSA that has become dominant. This strain - CC22 - has thrived by developing and maintaining multi-drug resistance, and becoming more fit to survive on hospital surfaces than other strains.>>>>

Levaquin Lawsuits

<https://www.lawyersandsettlements.com/search.html?keywords=levaquin>

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