



Fluoroquinolone Antibacterial Drugs for Systemic Use: Drug Safety Communication - Warnings Updated Due to Disabling Side Effects

[Posted 07/26/2016]

FDA 核准口服及注射劑型之 fluoroquinolones 類抗生素藥品更新仿單內容，包括

Avelox (moxifloxacin)

Cipro (ciprofloxacin)

Cipro extended-release (ciprofloxacin extended-release)

Factive (gemifloxacin)

Levaquin (levofloxacin)

Ofloxacin (generic brand)

以上抗生素與肢體障礙及潛在永久性之嚴重不良反應的發生有關，這些嚴重不良反應可能發生在肌腱、肌肉、關節、神經及中樞神經系統，且可能同時發生。因此 FDA 修訂仿單的警語、使用注意事項和用藥指引。

FDA 認為治療鼻竇炎、支氣管炎和非複雜性泌尿道感染時，應將全身性 fluoroquinolones 類抗生素保留至無其他替代治療選擇時使用，因為治療之風險大於其臨床效益。而針對一些嚴重感染的患者，當給予 fluoroquinolones 類抗生素的臨床效益大於嚴重不良反應風險時，fluoroquinolones 仍然可以作為一種治療選擇。

建議：

使用全身性 fluoroquinolones 類藥品時，若出現任何嚴重副作用（包括肌腱、關節或肌肉疼痛、讓人坐立不安的刺痛或發麻感覺、意識混亂及幻覺等），應立即聯絡您的醫療人員。若仍有任何疑問也應諮詢您的醫療人員。

醫療人員對於罹患鼻竇炎、支氣管炎和非複雜性泌尿道感染且有其它治療選擇時不應該開立全身性 fluoroquinolones 類藥品，因為治療之風險大於其臨床效益。另外，病患如果使用 Fluoroquinolon 後通報嚴重副作用時，也應該立即停藥，並使用非 Fluoroquinolon 藥物作替代治療。

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Including the following currently available fluoroquinolones

Avelox (moxifloxacin)

Cipro (ciprofloxacin)

Cipro extended-release (ciprofloxacin extended-release)

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Levaquin (levofloxacin)

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AUDIENCE: Family Practice, Infectious Disease, Neurology, Pharmacy, Patient

ISSUE: FDA approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection). These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient. As a result, FDA revised the Boxed Warning, FDA's strongest warning, to address these serious safety issues. In addition, FDA updated other parts of the drug label including the Warnings and Precautions and Medication Guide sections.

FDA has determined that fluoroquinolones should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis, acute exacerbation of chronic bronchitis, and uncomplicated urinary tract infections because the risk of these serious side effects generally outweighs the benefits in these patients. For some serious bacterial infections the benefits of fluoroquinolones outweigh the risks, and it is appropriate for them to remain available as a therapeutic option.

FDA is continuing to assess safety issues with fluoroquinolones as part of FDA's usual ongoing review of drugs and will update the public if additional actions are needed. See the FDA Drug Safety Communication for additional information, including a Data Summary and Additional Information for Health Care Professionals and Patients.

BACKGROUND: The labels of fluoroquinolone medicines already have a Boxed Warning for tendinitis, tendon rupture, and worsening of myasthenia gravis. The labels also include warnings about the risks of peripheral neuropathy and central nervous system effects. Other serious risks associated with fluoroquinolones are described in the labels, such as cardiac, dermatologic, and hypersensitivity reactions. After FDA's 2013 review that led to the additional warning that peripheral neuropathy may be irreversible, FDA evaluated post-marketing reports of apparently healthy patients who experienced disabling and potentially permanent side effects involving two or more body systems after being treated with a systemic fluoroquinolone

RECOMMENDATION: Patients must contact your health care professional immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include unusual joint or tendon pain, muscle weakness, a "pins and needles" tingling or pricking sensation, numbness in the arms or legs, confusion, and hallucinations. Talk with your health care professional if you have any questions or concerns (see List of Serious Side Effects from Fluoroquinolones in the FDA Drug Safety Communication).

Health care professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis

(ABECB), and uncomplicated urinary tract infections (UTI) because the risks outweigh the benefits in these patients. Stop fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient's treatment course.