



Fluoroquinolone Antibacterial Drugs: Drug Safety Communication – FDA Advises Restricting Use for Certain Uncomplicated Infections

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FDA 發布一則藥物安全警訊，Fluoroquinolone 相關的嚴重副作用所帶來的弊害大於其用於治療非複雜性感染的利益，這些感染包括鼻竇炎、支氣管炎、非複雜性的泌尿道感染，然而這些感染除了 Fluoroquinolone 仍有其他藥物可以做替代選擇。故 FDA 建議，限制 Fluoroquinolone 使用於某些非複雜性的感染。

當 Fluoroquinolone 作為全身性的藥物治療時，包括錠劑、膠囊、針劑的使用，都可能造成失能，甚至是永久性嚴重的傷害，這些傷害涉及肌肉、肌腱、關節、神經與中樞神經。

因此，FDA 要求所有 Fluoroquinolone 藥品仿單和用藥指引應更新以反映這一新的安全警訊。FDA 也會持續檢視與 Fluoroquinolone 相關的安全議題，並提供更多的資訊。

建議：

病患在服用 Fluoroquinolone 後，如果有肌腱、關節、肌肉疼痛，或是“如坐針氈”的刺痛感，意識混亂和幻覺等副作用，應立即通知醫療人員。

醫療人員一旦在病患通報 Fluoroquinolon 引起的嚴重副作用時，應該立即停藥，並使用非 Fluoroquinolon 藥物作替代治療。

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AUDIENCE: Internal Medicine, Family Practice, Pharmacy, Patient

ISSUE: FDA is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

As a result, FDA is requiring the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. FDA is continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.

See the FDA Drug Safety Communication for a list of currently available FDA approved fluoroquinolones for systemic use.

BACKGROUND: The safety issues described in the Drug Safety Communication were also discussed at an FDA Advisory Committee meeting in November 2015.

RECOMMENDATION: Patients should 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 tendon, joint and muscle pain, a “pins and needles” tingling or pricking sensation, confusion, and hallucinations. Patients should talk with your health care professional if you have any questions or concerns.

Health care professionals should stop systemic 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.