



Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj Kami : (25) dlm BPFK/17/FV/2.10

Tarikh : 12 DEC 2008

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Y. Bhg Dato'/Datin/Tuan/Puan,

**MAKLUMAT KESELAMATAN MENGENAI PRODUK ANTIMIKROBIAL
SISTEMIK KUMPULAN "FLUOROQUINOLONES"**

Adalah saya merujuk kepada perkara di atas.

2. USFDA telah membuat kajian analisa baru terhadap laporan kesan advers ubat dan mendapati bahawa penggunaan antimicrobial sistemik kumpulan "fluoroquinolones" telah dikaitkan dengan peningkatan risiko "tendonitis" dan "tendon rupture" terutamanya di kalangan pesakit berumur lebih daripada 60 tahun, sedang mengambil ubat "corticosteroids" dan pesakit "kidney, heart and lung transplant". Hasil kajian juga telah menunjukkan bahawa walaupun kesan advers "tendonitis" dan "tendon

rupture” telah dinyatakan di dalam sisip bungkusan, bilangan kesan advers tersebut masih banyak dilaporkan. Petikan perkara tersebut dilampirkan untuk perhatian dan makluman.

3. Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) telah menerima sebanyak 150 laporan kesan advers dari kumpulan fluoroquinolones dan satu laporan berkaitan dengan ‘tendonitis’ telah dilaporkan berikutan dengan penggunaan ubat pefloxacin. Berikutan dengan analisa keselamatan ubat dari kumpulan ini, Pihak Berkuasa Kawalan Dadah (PBKD) telah bersetuju bahawa maklumat keselamatan berikut perlu dinyatakan pada Seksyen “Special Warnings and Precaution for Use”:

Musculo-skeletal system:

“The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in people older than 60, in those taking corticosteroid drugs, and in kidney, heart, and lung transplant recipients. Patients experiencing pain, swelling, inflammation of a tendon or tendon rupture should be advised to stop taking their fluoroquinolone medication (to specify the active ingredient) and to contact their health care professional promptly about changing their antimicrobial therapy. Patients should also avoid exercise and using the affected area at the first sign of tendon pain, swelling, or inflammation”

4. Pengamal perubatan adalah diingatkan supaya dapat membuat pertimbangan sewajarnya mengenai risiko dan manfaatnya sebelum mempreskrib ubat dari kumpulan ini terutamanya pada pesakit-pesakit yang berisiko seperti di atas. Seterusnya semua pengamal perubatan dan ahli farmasi disarankan dapat memantau kesan advers ini dan melaporkan kepada MADRAC untuk tindakan selanjutnya. Adalah diharapkan maklumat ini dapat dipanjangkan kepada mereka yang berkenaan.

Sekian, terima kasih.

“BERKHIDMAT UNTUK NEGARA”

Saya yang menurut perintah,



(SELVARAJA SEERANGAM)

Pengarah Regulatori Farmasi
Biro Pengawasan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

S.K : Ketua Pengarah Kesihatan
Kementerian Kesihatan Malaysia

Setiausaha PBKD

Fluoroquinolone Antimicrobial Drugs

[Posted 07/08/2008] FDA notified healthcare professionals that a BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendonitis and tendon rupture in patients taking fluoroquinolones for systemic use.

Fluoroquinolones are associated with an increased risk of tendonitis 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.

Reference: MEDWATCH, July 8, 2008