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DEPARTMENT OF HEALTH
DRUG OFFICE

DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION

3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

11 Jul 2018

Dear Healthcare Professionals,

FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement that FDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects. The low blood sugar levels can result in serious problems, including coma, particularly in older people and patients with diabetes who are taking medicines to reduce blood sugar. FDA is making these changes because its recent review found reports of life-threatening low blood sugar side effects and reports of additional mental health side effects.

FDA is requiring these updates in the drug labels and to the patient Medication Guides for the entire class of fluoroquinolones. This affects only the fluoroquinolone formulations taken by mouth or given by injection.

Blood sugar disturbances, including high blood sugar and low blood sugar, are already included as a warning in most fluoroquinolone drug labels; however, FDA is adding that low blood sugar levels, also called hypoglycemia, can lead to coma.

Across the fluoroquinolone antibiotic class, a range of mental health side effects are already described under Central Nervous System Effects in the Warnings and Precautions section of the drug label, which differed by individual drug. The new label changes will make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are disturbances in attention, disorientation, agitation, nervousness, memory impairment, and serious disturbances in mental abilities called delirium.

FDA reviewed reports of cases submitted to FDA and the published medical literature of apparently healthy patients who experienced serious changes in mood, behavior, and blood sugar levels while being treated with systemic fluoroquinolones. Some of the mental health side effects are already listed in some of the labels and some events are listed using similar terms, but not all fluoroquinolone labels provided this information. As a result, FDA is requiring several changes to the Warnings and Precautions section in the fluoroquinolones drug labels. Details will be added describing hypoglycemic coma, and the new subheading “Psychiatric Adverse Reactions” found under “Central Nervous System Effects” will help clarify and identify the mental health side effects.

Patients should tell their healthcare professionals if they are taking a diabetes medicine when their healthcare professional is considering prescribing an antibiotic, and also if they have low blood sugar or symptoms of it while taking a fluoroquinolone. Early signs and symptoms of low blood sugar include: confusion, dizziness, feeling shaky, unusual hunger, headaches, irritability, pounding heart or very fast pulse, pale skin, sweating, trembling, weakness and unusual anxiety. Patients should also tell their healthcare professional immediately if they notice any changes in their mood, behavior, or thinking.

Healthcare professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin. Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose and stop fluoroquinolone treatment immediately if a patient reports any central nervous system side effects, including psychiatric adverse reactions, or blood glucose disturbances and switch to a non-fluoroquinolone antibiotic if possible.

Please refer to the following website in FDA for details:

<https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm>

In Hong Kong, there are 188 registered pharmaceutical products containing fluoroquinolones which are oral preparations or injectables for use in human, including ciprofloxacin (81 products), levofloxacin (62), moxifloxacin (5), norfloxacin (7), ofloxacin (31), sparfloxacin (1) and prulifloxacin (1). All products are prescription-only medicines. So far, the Department of Health (DH) has received 4 cases of adverse drug reaction related to levofloxacin and 1 case related to moxifloxacin, but these cases are not related to hypoglycemia or mental health side effects. The DH has not received any case of adverse drug reaction related to other fluoroquinolones. In light of the above FDA’s announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'Joseph Lee', written in a cursive style.

(Joseph LEE)

for Assistant Director (Drug)