# FDA Warns of Risks with Unapproved Use of Malaria Drug Qualaquin

**SERIOUS SIDE EFFECTS REPORTED WHEN USED TO TREAT OR PREVENT NIGHT TIME LEG CRAMPS**

The United States Food and Drug Administration today warned that the unapproved use of the malaria drug Qualaquin (quinine sulfate) to treat night time leg cramps has resulted in serious side effects and prompted the manufacturer to develop a risk management plan aimed at educating health care professionals and patients about the potential risks.

Qualaquin is not FDA-approved to treat or prevent night time leg cramps.

A review of reports submitted to the FDA's Adverse Event Reporting System (AERS) between April 2005 and Oct. 1, 2008, found 38 United States cases of serious side effects associated with the use of quinine, the active drug in Qualaquin.

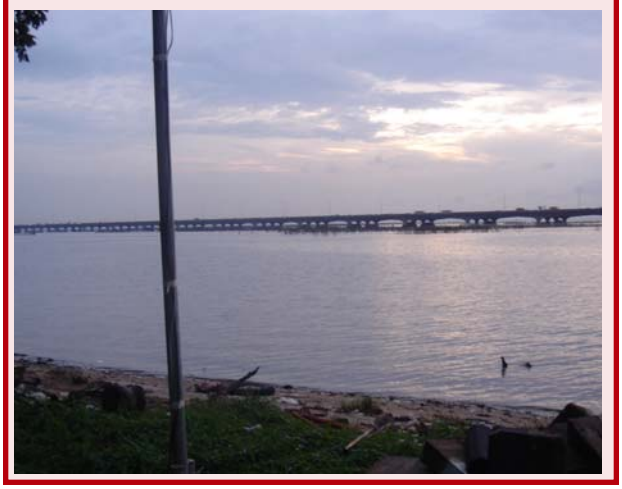
Quinine use resulted in serious and life-threatening reactions in 24 cases, including low level of platelets in the blood (thrombocytopenia), and hemolytic uremic syndrome/thrombotic thrombocytopenic purpura, a blood disorder that results in clots in small blood vessels around the body that can be accompanied by kidney impairment.

In some patients, these side effects resulted in permanent kidney impairment and hospitalization. Two patients died. Most of those reporting serious side effects took the drug to prevent or treat leg cramps or restless leg syndrome.

The risk management plan, called a Risk Evaluation



***Early morning scenes on the University of Lagos campus, Nigeria. Nigeria is the largest malaria-endemic country in the world, and bears the burden of the greatest number of deaths, according to WHO. Pictures were taken by MJoTA Publisher while a guest of Dean of Pharmacy, Professor Dr David Ifudu and his wife Mrs Efe Ifudu RD.***



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and Mitigation Strategy (REMS), requires that patients be given a Medication Guide explaining what Qualaquin is and is not approved for, as well as the potential side effects of the drug. The company is also required to issue a Dear Health Care Provider Letter warning of the potential risk of serious and life-threatening blood-related (hematologic) reactions.

"Health care professionals and patients should be aware that FDA has not approved the use of Qualaquin for the treatment or prevention of night time leg cramps," said Edward Cox MD, MPH, director, Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research. "FDA has received reports that some patients have developed serious side effects when taking quinine for night time leg cramps."

Qualaquin was approved by the FDA in August 2005 to treat uncomplicated malaria caused by the parasite Plasmodium falciparum, an infection that can be life-threatening if untreated. According to the U.S. Centers for Disease Control and Prevention, about 1,500 cases of malaria are diagnosed in the United States each year, primarily resulting from travel abroad.

Qualaquin is marketed by Philadelphia-based AR Scientific.

Health care professionals and patients may report serious adverse events (side effects) to the FDA's MedWatch Adverse Event Reporting program online at www.fda.gov, by regular mail, fax, or phone.

By mail, send postage-paid, pre-addressed Form FDA 3500 to the address on the pre-addressed form.

Fax: 800-FDA-0178

Phone: 800-332-1088

***CDC: Centers for Disease Control and Prevention.***

***FDA: Food and Drug Administration***