FDA WARNING: Qualaquin unapproved for use for night leg cramps due to serious side effects

By Catherine Bertram - July 11, 2010

The FDA issued a warning this week due to continued reports of serious side effects in patients using Qualaquin "off-label" for night time leg cramps, it states in part as follows "FDA has approved a risk management plan to warn against the use of this drug for such unapproved uses. Qualaquin should not be used for night time leg cramps. Qualaquin use may result in serious and life-threatening hematological reactions, including serious bleeding due to thrombocytopenia, and hemolytic-uremic syndrome/ thrombotic thrombocytopenic purpura, which in some cases may result in permanent kidney damage. In some patients, adverse reactions result in hospitalization and death.

Qualaquin is only FDA-approved for the treatment of uncomplicated malaria caused by the parasite Plasmodium falciparum, primarily in travelers returning from malaria-endemic areas. However, the majority of Qualaquin's use in the United States is for the treatment or prevention of night time leg cramps.The product labeling states that the risks associated with the use of Qualaquin in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps outweigh any potential benefits.

The risk management plan (REMS) requires that patients be given a Medication Guide explaining what this medication is and is not approved for, as well as the potential side effects of this drug. In addition, the REMS requires that the manufacturer issue a Dear Health Care Provider Letter warning of the risk of serious and life-threatening hematologic reactions.

THE FDA RECOMMENDATION:

Healthcare professionals should discuss with patients the warning signs of thrombocytopenia, such as easy bruising, severe nose bleeds, blood in the urine or stool, bleeding gums, and the appearance of unusual purple, brown, or red spots on the skin.

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