



[Home](#) > [Drugs](#) > [Drug Safety and Availability](#) > [Postmarket Drug Safety Information for Patients and Providers](#)

Drugs

FDA Drug Safety Communication: New risk management plan and patient Medication Guide for Qualaquin (quinine sulfate)

Safety Announcement

[Additional Information for Patients](#)

[Additional Information for Healthcare Professionals](#)

[Data Summary](#)

Safety Announcement

[07-08-2010] Due to continued reports of serious side effects in patients using Qualaquin "off-label" (a non-FDA-approved use) for night time leg cramps, the U.S. Food and Drug Administration (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 is ONLY FDA-approved for the treatment of uncomplicated malaria caused by the parasite *Plasmodium falciparum*, a rare infection in the United States, 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, a use NOT approved by FDA.

Qualaquin use may result in serious and life-threatening blood-related (hematological) reactions, including serious bleeding due to a severe lowering of blood cells called platelets (thrombocytopenia), and a condition known as 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.

The risk management plan, called a Risk Evaluation and Mitigation Strategy (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 (DHCP) Letter warning of the risk of serious and life-threatening hematologic (blood-related) reactions.

Healthcare professionals and patients should know that Qualaquin is not approved for the treatment or prevention of night time leg cramps. The product labeling further 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.

Additional Information for Patients

- Qualaquin is only approved for the treatment of a certain type of malaria (uncomplicated) caused by the parasite *Plasmodium falciparum*—a rare infection in the United States (approximately 1500 cases per year) primarily resulting from travel abroad.
- Qualaquin is not approved for the treatment or prevention of night time leg cramps. Patients using Qualaquin for this condition are at risk for serious side effects.
- If you are taking Qualaquin for night time leg cramps, you should discuss other treatment options with your healthcare professional.
- If you experience easy bruising, severe nose bleeding, blood in your urine or stool, bleeding gum, or the appearance of unusual purple, brown, or red spots on your skin, contact your healthcare professional immediately.
- Read the *Medication Guide* given to you at the pharmacy when you pick up a prescription for Qualaquin. It explains the serious risks associated with the use of Qualaquin that you should be aware of.
- Report any side effects with the use of Qualaquin to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

- Qualaquin is only approved for the treatment of uncomplicated malaria caused by the parasite *Plasmodium falciparum*.
- Qualaquin is NOT approved for the treatment or prevention of night time leg cramps. Prescribing Qualaquin for this condition exposes patients to risk for serious adverse events.
- 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.
- Encourage patients to read the *Medication Guide* given to them at the pharmacy before starting Qualaquin and each time they get a refill.
- Report adverse events to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of this page.

Data Summary

A review of reports submitted to FDA's Adverse Event Reporting System (AERS) from April 2005 to October 1, 2008, found 38 U.S. cases of serious adverse events associated with quinine, the active drug in Qualaquin. The majority of patients (25) took quinine to prevent or treat leg cramps or Restless Leg Syndrome; only 1 patient was taking quinine for the treatment of malaria.

Among the 38 reports, there were 24 hematologic events, four cardiovascular events, and 10 miscellaneous adverse events such as gastrointestinal symptoms, hearing loss, rash, electrolyte imbalance, and drug interaction. This data summary focuses on the reports of hematologic adverse events.

Of the 24 patients with reported hematologic adverse events:

- Median time-to-onset of adverse events after starting quinine was 13.5 days.
- Twenty-one patients had a diagnosis of thrombocytopenia and required hospitalization. Of these, 18 reports provided data on platelet

count:

- median platelet count: 4500 cells/ μ L
- case range: 1000 - 83,000 cells/ μ L; (normal range: 150,000 - 450,000 cells/ μ L).
- Twelve reports noted that patients had mucosal bleeding (gingival, gastrointestinal, epistaxis), hemoptysis, petechiae, or ecchymosis.
- Four cases of thrombocytopenia were further classified as thrombotic thrombocytopenic purpura (TTP) (2) and idiopathic thrombocytopenic purpura (ITP) (2).
- Two deaths were reported (one due to TTP and one due to hemolysis).
- Most of the patients with thrombocytopenia recovered when quinine was discontinued and other therapeutic interventions were initiated.

Related Information

- [Quinine Sulfate \(marketed as Qualaquin\) Information](#)¹
- [Using Malaria Medication for Leg Cramps is Risky](#)²
Potentially life-threatening side effects
- [FDA Warns of Risks with Unapproved Use of Malaria Drug Qualaquin](#)³
7/8/2010

Contact Us

- **Report a Serious Problem**
- 1-800-332-1088
- 1-800-FDA-0178 Fax
- [MedWatch Online](#)⁴
- **Regular Mail:** Use postage-paid [FDA Form 3500](#)⁵
- **Mail to:** MedWatch 5600 Fishers Lane
Rockville, MD 20857

Links on this page:

1. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm217593.htm>
2. <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm217599.htm>
3. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218383.htm>
4. <http://www.fda.govhttps://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
5. <http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf>