

SPINE SAFETY WARNING:

Information for Healthcare Professionals: Drug Safety Labeling Changes - Qalakin (quinine sulfate) 324 mg capsules

According to MedWatch, FDA notified healthcare professionals that the BOXED WARNINGS, WARNINGS and MEDICATION GUIDE text for Qalakin have been updated. The following sentences have been added to the labeling:

BOXED WARNING

Warning

- Qalakin use for the treatment or prevention of nocturnal leg cramps may result in serious and life-threatening hematologic reactions, including thrombocytopenia and hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP). Chronic renal impairment associated with the development of TTP has been reported. The risk associated with Qalakin use in the absence of evidence of its effectiveness in the treatment or prevention of nocturnal leg cramps outweighs any potential benefit.

WARNINGS

Use of Qalakin for Treatment or Prevention of Nocturnal Leg Cramps

- Qalakin may cause unpredictable serious and life-threatening hematologic reactions including thrombocytopenia and hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP)
- Chronic renal impairment associated with the development of TTP

Thrombocytopenia

- Quinine-induced thrombocytopenia is an immune-mediated disorder. Severe cases of thrombocytopenia that are fatal or life threatening have been reported, including cases of HUS/TTP. Chronic renal impairment associated with the development of TTP has also been reported. Thrombocytopenia usually resolves within a week upon discontinuation of quinine. If quinine is not stopped, a patient is at risk for fatal hemorrhage. Upon re-exposure to quinine from any source, a patient with quinine-dependent antibodies could develop thrombocytopenia that is more rapid in onset and more severe than the original episode.

MEDICATION GUIDE

- Patient Package Insert has been converted into a Medication Guide to incorporate additional safety information

Read the complete summary of MedWatch safety labeling changes at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm194391.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>.

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