澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

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由
De/From:
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致: 醫生、藥劑師及其他衛生專業人士
Para/To: Physicians, pharmacists and other healthcare professionals
主題: 關於奎寧(quinine)安全性的最新資訊
Ass./Subject: Latest safety update on quinine
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隨件附上一則關於奎寧(quinine)安全性的最新資訊, 請醫生、藥劑師及其他衛生專業人士參閱, 如台端懷疑由上述或其他藥物引致的任何不良反應, 請以下列任一方式向本廳通報：

- 網上通報 - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- 郵寄 - 澳門士多烏拜斯大馬路 51號 華仁中心二樓
- 傳真 – 28524016

通報人士可親臨藥物事務廳索取或在http://www.ssm.gov.mo/design/services/serpt_chn.pdf網址上下載通報表格。如有任何疑問, 請於辦公時間致電85983517或85983439與藥物監測暨管理處楊燕雯藥劑師或林俊耀藥劑師聯絡, 倘遇緊急的情況, 亦可於非辦公時間傳呼85008068。

謹祝 台安!

Attached herewith is the latest safety update on quinine for your reference. If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of the above or any other medication, please report through any of the following methods：

- Online - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2nd Floor, Macao S.A.R., China
- Fax to - 853-28524016

The report form can be collected in person at Department of Pharmaceutical Affairs or downloaded from the website designated as http://www.ssm.gov.mo/design/services/serpt_chn.pdf. Should you have any query, please contact Ms. Beatrice Young or Mr. Jeffrey Lam at 8598-3517 or 8598-3439 respectively from the Division of Pharmacovigilance and Pharmacoeconomics during office hours. In case of urgent situations during off hours, please page 85008068.

Thanking you in advance for your attention!

藥物事務廳廳長
Chief, Department of Pharmaceutical Affairs

蔡炳祥
Choi Peng Cheong

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主題：關於奎寧(quinine)安全性的最新資訊
Subject：Latest safety update on quinine

由於使用奎寧(quinine)於夜間腿抽筋(night time leg cramps)一類未獲核准的適應症時，持續有嚴重不良反應的報告，美國食物及藥物管理局(USFDA)警告不要處方該藥於此未批准的用途。目前quinine只獲批准用於治療由惡性瘧原蟲(*Plasmodium falciparum*)引起的非複雜性瘧疾(uncomplicated malaria)，這一罕見的傳染病主要發生於自瘧疾流行地區歸來的旅遊人士，並不可用於治療夜間腿抽筋。

使用quinine可引起嚴重且致命的血液不良反應，包括由於血小板減少(thrombocytopenia)而導致的嚴重出血，以及可導致某些病人永久腎損害的溶血尿毒綜合症(hemolytic-uremic syndrome)或血栓性血小板減少性紫癜(thrombotic thrombocytopenic purpura)，這些不良反應甚至導致某些病人住院和死亡。目前並沒有證據顯示該藥可用於預防或治療夜間腿抽筋，用於該適應症的風險高於其潛在的效益。

基於此，衛生專業人士應掌握以下資訊：

- Quinine只批准用於治療由*Plasmodium falciparum*引起的非複雜性瘧疾。
- Quinine並未獲批准用於預防或治療夜間腿抽筋，使用quinine於該適應症時可導致病人出現嚴重的不良反應。
- 告知病人警惕出現血小板減少的症狀，如容易瘀傷、嚴重鼻出血、尿液或糞便帶血、牙齦出血以及皮膚出現不尋常的紫色、棕色或紅色斑點。

藥物監測暨管理處

Due to continued reports of serious side effects in patients using quinine "off-label" for night time leg cramps, the U.S. Food and Drug Administration (USFDA) warned against the use of this drug for such unapproved uses. Quinine is ONLY approved for the treatment of uncomplicated malaria caused by the parasite *Plasmodium falciparum*, a rare infection primarily in travelers returning from malaria-endemic areas. Quinine should not be used for night time leg cramps.

Quinine use may result in serious and life-threatening blood-related (hematological) reactions, including serious bleeding due to 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 absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps outweigh any potential benefits.

Information for Healthcare Professionals

- Quinine is only approved for the treatment of uncomplicated malaria caused by the parasite *Plasmodium falciparum*.
- Quinine is NOT approved for the treatment or prevention of night time leg cramps. Prescribing Quinine 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.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website：

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm218424.htm
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm218202.htm