



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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De/From: 部門/Dept.: 藥物事務廳 Department of Pharmaceutical Affairs

簽署者/Ass./Signat.: 蔡炳祥廳長 Dr. Choi Peng Cheong – Department Chief

傳真機/Fax: (853)-28524016

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dronedarone (Multaq®)和moxifloxacin (Avelox®)安全性的最新資訊

Ass./Subject: Latest safety updates on dronedarone (Multaq®) and moxifloxacin (Avelox®)

頁數: 1/3

Nº folhas/N.pages:

隨件附上兩則分別關於dronedarone (Multaq®)和moxifloxacin (Avelox®)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 - 澳門士多鳥拜斯大馬路 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 are latest safety updates on dronedarone (Multaq®) and moxifloxacin (Avelox®). 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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● Dronedarone (Multaq[®])與嚴重肝損傷

Dronedarone (Multaq[®])用於過往6個月出現心房顫動或心房撲動的病人，美國食物及藥物管理局(USFDA)通知衛生專業人士有關使用該藥具有潛在嚴重肝損傷的風險。USFDA收到多宗罕見的嚴重肝損傷個案，包括兩宗急性肝衰竭繼而需要肝移植的上市後通報個案。基於此，建議醫生、藥劑師及其他衛生專業人士：

- i) 考慮於治療過程中進行定期的血清肝酶和膽紅素檢測，尤其在治療的首6個月。
- ii) 如懷疑出現了肝損傷，停止使用Multaq[®]，並且立即檢測血清肝酶和膽紅素，如證實出現了肝損傷，應採取適當的治療措施。
- iii) 如並未發現引致病人出現肝損傷的其他可能原因，不要對該病人重新使用Multaq[®]。
- iv) 建議病人如服用Multaq[®]時出現肝損傷或毒性的症狀，包括厭食、噁心、嘔吐、發熱、疲倦、右上腹疼痛、黃疸、尿夜變深或痕癢，須立即向醫生求診。

● Moxifloxacin (Avelox[®])作為第二綫用藥

基於近期數據指出使用moxifloxacin (Avelox[®])可增加致命的肝臟毒性及包括QT間期延長在內的嚴重不良反應的風險，英國藥物管理局(MHRA)發出通告，指Avelox[®]只應用於其他常用的第一綫抗生素治療無效或不能使用的輕、中度盆腔炎、急性細菌性鼻竇炎、慢性支氣管炎急性發作以及社區獲得性肺炎(嚴重個案除外)的病人。

藥物監測暨管理處

● Dronedarone (Multaq[®]) and severe hepatic injury

The United States Food and Drug Administration (USFDA) notified healthcare professionals about the potential risk of liver injury associated with dronedarone (Multaq[®]), a drug indicated for patients with atrial fibrillation (AF) or atrial flutter for the past six months. The Agency received cases of rare, but severe hepatic injury, including two post-marketing cases of acute liver failure requiring subsequent liver transplants. In view of this observation the following recommendation are advised for the physicians, pharmacists and other healthcare professionals :

- i) consider obtaining periodic hepatic serum enzymes and bilirubin especially during the first 6 months of treatment.
- ii) if hepatic injury is suspected, discontinue Multaq[®] and request testing on serum liver enzymes and bilirubin immediately. If hepatic injury is found, appropriate treatment should be initiated.
- iii) do not restart Multaq[®] in patients who experience hepatic injury without another explanation for the observed liver injury.
- iv) advise patients to seek medical help immediately if they experience signs and symptoms of hepatic injury or toxicity (anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching) while taking Multaq[®].



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- Reserve oral moxifloxacin (Avelox[®]) for second-line use
As recent data indicated an increased risk of life-threatening liver reactions and other serious risks (such as QT interval prolongation) are associated with the use of moxifloxacin(Avelox[®]), the British Medicine and Health Products Regulatory Agency (MHRA) announced that Avelox[®] should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections namely mild to moderate pelvic inflammatory disease(PID), acute bacterial sinusitis, acute exacerbations of chronic bronchitis, and community acquired pneumonia (except severe cases).

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites :

<http://www.fda.gov/Drugs/DrugSafety/ucm240011.htm>

<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON105760>