



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

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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: 關於質子泵抑制劑和abacavir安全性的最新資訊

Ass./Subject: Latest safety updates on proton pump inhibitors(PPIs) and abacavir

頁數: 1/3

Nº folhas/N.pages:

隨件附上一則關於質子泵抑制劑和abacavir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 are latest safety updates on proton pump inhibitors(PPIs) and abacavir. 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
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● 長期服用質子泵抑制劑與低鎂血症

美國食物及藥物管理局(USFDA)回顧了長期服用質子泵抑制劑(proton pump inhibitors, PPIs)的病人出現低鎂血症的個案後, 指出病人長期(多於1年)服用質子泵抑制劑與出現低鎂血症存在關聯性, 病人的症狀可能很嚴重, 包括手足抽搐、心律失常以及驚厥等, 醫生可向病人處方鎂製劑以緩解症狀, 如單獨使用鎂製劑不能改善由血清鎂水平過低所引致的嚴重不良反應, 病人須停止使用PPIs。基於上述原因, 建議醫生、藥劑師及其他衛生專業人士:

- i) 熟悉低鎂血症的症狀以及可能引致該情況的原因(包括藥物);
- ii) 當病人併用PPIs和digoxin、利尿劑或其他可能引致低鎂血症的藥物, 可能會出現低鎂血症;
- iii) 於開始PPIs治療前和長期治療期間, 建議定期為病人檢測血清鎂水平;
- iv) 如病人出現低鎂血症, 特別是出現上述症狀時, 應懷疑是由PPIs引致;
- v) 對出現低鎂血症的病人, 除補充鎂製劑外, 可能還需要停止服用PPIs;
- vi) 教導正在服用PPIs的病人了解低鎂血症的症狀, 包括不規則的心跳、肌肉痙攣、震顫或驚厥, 如出現上述症狀, 應立即求診。

● Abacavir與心肌梗塞的風險

由於上市後數據與生產商的資料對於abacavir是否增加心肌梗塞的風險存在分歧, 美國食物及藥物管理局(USFDA)對26個關於abacavir的隨機臨床試驗作綜合分析(meta-analysis)後, 指出abacavir不會增加病人出現心肌梗塞的風險。目前, 建議醫生繼續根據說明書所述的劑量處方abacavir, 以及教導正在服用abacavir的病人, 在沒有醫生的指示下不能擅自停止服用該藥。

藥物監測暨管理處

● Prolonged treatment with proton pump inhibitors(PPIs) and hypomagnesemia

United States Food and Drug Administration(USFDA) completed the review over cases of hypomagnesemia in patients after prolonged treatment with proton pump inhibitors (PPIs). Result of the above suggests a positive association between prolonged use(longer than 1 year) of protein pump inhibitors and development of hypomagnesemia in patients which can be serious and is characterized by patients experiencing tetany, arrhythmias, and convulsions. To remedy this condition magnesium supplements should be prescribed to the vulnerable patients. If replenishment of magnesium supplementation alone does not improve the serious adverse symptoms of low serum magnesium level, the PPIs should be discontinued. In light of the above, we advise physicians, pharmacists and other healthcare professionals:

- i) to be familiar with the signs of hypomagnesemia and the causes(including drugs) that may lead to this condition;
- ii) to recognize hypomagnesemia may be associated with patients who are also concurrently taking PPIs with medications such as digoxin, diuretics or drugs that may cause hypomagnesemia;
- iii) to consider obtaining serum magnesium levels before initiating and periodically during the course of long and extended PPIs treatment;
- iv) to consider PPIs as a possible cause of hypomagnesemia, particularly in patients who are clinically symptomatic;
- v) to be cognizant that patients who develop hypomagnesemia may require PPI discontinuation in addition to magnesium replacement;
- vi) to educate patients about the signs of hypomagnesemia, e.g. irregular heart beats, muscle spasm, tremors, or seizures while taking PPIs and to seek for immediate medical care while the above symptoms occur.



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● **Abacavir and risk of myocardial infarction**

As conflicting results about whether abacavir treatment may increase the risk of developing myocardial infarction emerged between the postmarketing observation and the manufacturer's database, the United States Food and Drug Administration (USFDA) conducted a meta-analysis evaluation of 26 randomized clinical trials relating to the use of abacavir which did not show an increased risk of myocardial infarction associated with abacavir treatment. At this moment, physicians are advised to continue prescribing abacavir according to the professional label and to inform those patients being treated with abacavir, not to stop taking the medication without first talking to their physicians.

Division of Pharmacovigilance
and Pharmacoeconomics (DFF)

參考資料/Reference and website :

<http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm>

<http://www.fda.gov/Drugs/DrugSafety/ucm245164.htm>