



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

No.1

參照編號 0922/DAF/10
Nº ref.

日期: 13/08/2010
Data/Date:

由

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lamotrigine安全性的最新資訊

Ass./Subject: Latest safety update on lamotrigine

頁數: 1/2

Nº folhas/N.pages:

隨件附上一則關於lamotrigine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 lamotrigine 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



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

主題： 關於lamotrigine安全性的最新資訊
Subject： Latest safety update on lamotrigine

Lamotrigine為治療二歲以上兒童的驚厥(seizures)和成年人的雙極(燥狂-抑鬱)症(bipolar disorder)的藥物，美國食物及藥物管理局(USFDA)回顧該藥的不良反應報告後，發現自該藥於1994年上市，至2009年11月期間，共有40宗兒童和成年病人使用lamotrigine後出現無菌性腦膜炎(aseptic meningitis)的個案，症狀包括頭痛、發熱、頸部僵硬、噁心、嘔吐、皮疹以及對光過敏。

基於腦膜炎的嚴重性以及必須儘快診斷其病因和進行治療，對於正在服用lamotrigine的病人，醫生、藥劑師及其他衛生專業人士應注意該藥可引起無菌性腦膜炎，教導病人腦膜炎的相關症狀，如病人出現上述症狀，應仔細評估其他可能引致病人出現腦膜炎的原因以及對症治療。如沒有其他引致腦膜炎的明確原因，應考慮停止使用lamotrigine。

備註：獲准在本澳市場供應含lamotrigine的藥物包括APO-lamotrigine Tab 100mg、Lamictal Dispersible Tab 5mg/25mg、Lamictal Tab 50mg/100mg、Latrigine Tab 100mg “Kingdom”、PMS-Lamotrigine Tab 25mg/100mg以及U-CHU Lamogin Tab 100mg。

藥物監測暨管理處

Lamotrigine is a medication commonly used for seizures in children two years and older, and bipolar disorder in adults. Based on United States Food and Drug Administration(USFDA)'s review of adverse event reports submitted to the agency from December 1994 (when the drug was approved) through November 2009, a total of 40 cases of aseptic meningitis occurring in pediatric and adult patients taking lamotrigine were identified. Symptoms of meningitis may include headache, fever, stiff neck, nausea, vomiting, rash, and sensitivity to light.

In light of the severity of meningitis, it is important to rapidly diagnose the underlying cause so that treatment can be promptly initiated. For those patients taking lamotrigine, physicians, Pharmacists and other healthcare professionals should be aware that lamotrigine can cause aseptic meningitis and educate their patients signs and symptoms of meningitis. If meningitis is suspected, patients should also be evaluated for other causes of meningitis and treated as indicated. Discontinuation of lamotrigine should be considered if no other clear cause of meningitis is identified.

Note：The lamotrigine authorized for distribution in the Macao market include APO-lamotrigine Tab 100mg、Lamictal Dispersible Tab 5mg/25mg、Lamictal Tab 50mg/100mg、Latrigine Tab 100mg “Kingdom”、PMS-Lamotrigine Tab 25mg/100mg and U-CHU Lamogin Tab 100mg.

Division of Pharmacovigilance
and Pharmacoeconomics(DFP)

參考資料/Reference and website：

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm222269.htm>

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm221847.htm>