



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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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: 關於拉米夫定(lamivudine)和替比夫定(telbivudine)安全性的最新資訊

Ass./Subject: Latest safety update on lamivudine and telbivudine

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Nº folhas/N.pages:

隨件附上一則關於拉米夫定(lamivudine)和替比夫定(telbivudine)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 lamivudine and telbivudine 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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橫紋肌溶解(rhabdomyolysis)是使用拉米夫定(lamivudine)和替比夫定(telbivudine)時所可能出現嚴重的不良反應，雖然這兩個藥物的說明書已明確描述該不良反應，但鑒於該不良反應的及時發現、診斷和治療對患者的預後有利，國家食品藥品監督管理局再次提醒衛生專業人士，警惕lamivudine和telbivudine引起橫紋肌溶解的風險，該局的藥品不良反應監測中心近期發佈的《第30期藥品不良反應信息通報》中，指某些病人使用了lamivudine或telbivudine後，出現了嚴重的橫紋肌溶解。

基於以上事實，建議醫生：

- 處方上述藥物予病人時應謹慎，充分考慮患者的病情以及可能潛在的風險。
- 告知病人關於上述藥物潛在的風險。
- 監測病人某些生理指標的改變，包括：
 - 肌酸磷酸激酶水平
 - 肝、腎功能
 - 出現彌漫性肌肉疼痛、肌肉觸痛、肌無力、關節痛等症狀
- 一旦患者出現上述症狀，應立即停藥或採取相應的治療措施，對於出現嚴重橫紋肌溶解的病人，積極的救治措施能避免患者發生危及生命的代謝紊亂和急性腎功能衰竭

藥物監測暨管理處

It is a well-acknowledged fact that patients, who were being treated with lamivudine and telbivudine, may develop rhabdomyolysis as a serious adverse reaction. Such condition was a well-known drug reaction listed on the product information of aforementioned medications. However, the National Adverse Drug Reaction Monitoring (NADRM) Center under State Drug and Food Administration (SFDA), China, reiterated on her "ADR Information Bulletin - No. 30th Issue" describing case(s) of patients experiencing serious rhabdomyolysis upon the administration of lamivudine and telbivudine. The purpose of her article serves as a reminder for all healthcare professionals to be aware of the adverse drug observation on these medications and to be able to identify, detect, diagnose and treat the patient(s) early enough for better prognosis and to hasten their recovery.

In view of the above, we would like to offer physicians the following advice:

- exercise caution and conduct a thorough consideration incorporating patients' disease states and possible and potential risks before selecting the drug of choice for a patient.
- educate patients about the potential risks of these drug(s).
- be vigilantly attentive about changes on patients'
 - creatine kinase levels
 - liver and kidney function tests
 - developing diffuse muscle pain, muscle tenderness, muscle weakness, joint pain and other symptoms
- discontinue the causative drug immediately or take appropriate measures as required if patient develops any of the above. For patients developing severe rhabdomyolysis while on treatment, initiate active treatment measures immediately can prevent life-threatening metabolic disorders and acute renal failure.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

衛生局格式064/ www.sfda.gov.cn/WS01/CL0050/51601.html

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