



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Zerit® (stavudine)安全性的最新資訊

Ass./Subject: Latest safety update on Zerit® (stavudine)

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Nº folhas/N.pages:

隨件附上一則關於Zerit® (stavudine)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63009255。

謹祝 台安!

Attached herewith is the latest safety update on Zerit® (stavudine). 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 63009255.

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Zerit[®] (stavudine)安全性的最新資訊
Subject : Latest safety update on Zerit[®] (stavudine)

最新的上市後數據和文獻顯示，相對其他治療HIV感染的藥物發生嚴重不良反應的機率，服用Zerit[®] (stavudine)的病人出現嚴重不良反應的潛在風險較高。在相關研究中，Zerit[®]引致乳酸酸中毒的發生率大約是1%，當中死亡率為30~50%。相對其他核苷逆轉錄酶抑制劑(NRTIs)，使用Zerit[®]出現脂肪萎縮的風險大增，這不良反應的發生率和嚴重性隨時間增加，而且一般不會於停藥後完全逆轉。此外，使用Zerit[®]的病人高達20%出現外周神經炎，而且會因病人曾有神經病變或其他危險因子(如過量服用酒精，併用如isoniazid等藥物以及腎功能損傷)而增加該不良反應出現的機率。

基於上述結果，Bristol-Myers Squibb對Zerit[®]的適應症作出限制，規定只有當其他治療方案無效時，才可使用Zerit[®]，並儘可能使用最短的療程。

藥物監測暨管理處

Latest post-marketing data and published literatures comparing the occurrence of severe side effects of Zerit[®] (stavudine) with alternative HIV treatments concluded that there are increased risks of potentially severe side effects in patients taking Zerit[®]. Accordingly, the incidence rate of Zerit[®]-induced lactic acidosis occurred at around 1% on the studies and trials with a fatality rate of 30-50%. The risk of developing lipoatrophy in patients receiving Zerit[®] as compared to other nucleoside reverse transcriptase inhibitors (NRTIs) was greatly elevated, both the incidence and severity of this adverse reaction were cumulative over time and often not completely reversible on stopping Zerit[®]. Peripheral neuropathy was reported up to 20% in patients receiving Zerit[®] and would be aggravated in those patients with a history of neuropathy or other risk conditions that might have compromised them (e.g. excessive alcohol intake, on concomitant medications e.g. isoniazid and renal impairment) for developing this adverse reaction. In light of these results Bristol-Myers Squibb announced a restrictive indication for Zerit[®] stating that this medication should only be used when there are no alternatives, and for the shortest period of time possible.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmesagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsoonthesafetyofmedicines/C ON111795>