



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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由

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Exelon®貼片(rivastigmine經皮貼片)安全性的最新資訊

Ass./Subject: Latest safety update on Exelon® patch(rivastigmine transdermal patch)

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隨件附上一則關於Exelon®貼片(rivastigmine經皮貼片)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Exelon®貼片(rivastigmine經皮貼片)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 Exelon® patch(rivastigmine transdermal patch) for your reference. If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of Exelon® patch(rivastigmine transdermal patch) 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
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主題：關於Exelon[®]貼片(rivastigmine經皮貼片)安全性的最新資訊

Subject : Latest safety update on Exelon[®] patch(rivastigmine transdermal patch)

諾華公司(Novartis)與加拿大衛生部(Health Canada)通知衛生專業人士, 錯誤使用Exelon[®]貼片(rivastigmine經皮貼片)可造成rivastigmine過量的吸收, 引致嚴重的不良事故, 包括死亡。基於此, 諾華公司提醒衛生專業人士適當使用Exelon[®]貼片的重要性, 同時需教導病人及其照護者正確使用Exelon[®]貼片的技巧。而諾華公司亦對Exelon[®]貼片的說明書作出以下修改, 進一步強化該藥的安全性資訊:

- 於開始治療前, 醫生、藥劑師及相關衛生專業人士應教導病人及其照護者使用Exelon[®]貼片的適當方法, 並建議他們嚴格按指示用藥。
- 每天只應使用一塊Exelon[®]貼片, 建議固定用藥於背部的上/下部、手臂上部或胸部。
- 貼片使用了24小時之後, 必須將舊有貼片移除, 才能將另一塊貼片貼於新處。
- 不應將貼片剪成小塊。
- 當發生用藥過量(症狀包括噁心、嘔吐、腹瀉、高血壓、幻覺、流汗、呼吸抑制及驚厥等)的情況, 應將所有Exelon[®]貼片移除下來, 並送醫就診。

Novartis Pharmaceuticals Canada Inc., in consultation with Health Canada, would like to inform health professionals that serious adverse events including death, have occurred following rivastigmine overdose due to medication errors /misuse of Exelon[®] patch. Therefore, Novartis would like to remind health professionals of the importance of the proper use and application of Exelon[®] patch and the need to instruct patients and caregivers on correct application techniques for the use of Exelon[®] patch. The Exelon[®] patch Product Monograph is being revised to further emphasize the following safety information:

- Physicians, pharmacists and other healthcare professionals should inform patients and caregivers on the proper use of Exelon[®] patch prior to initiating therapy, and advise them to strictly follow instructions on patch usage.
- Only one transdermal patch should be applied per day to healthy skin on one of the recommended locations: the upper or lower back, or upper arm or chest.
- The previous day's patch must be removed before applying a new patch to a different skin location after 24 hours of use.
- The patch should not be cut into pieces.
- In case of overdose(symptoms including nausea, vomiting, diarrhea, hypertension, hallucinations, salivation, sweating, respiratory depression and convulsions), all Exelon[®] transdermal patches should be immediately removed and the patient should be evaluated by a physician.

參考資料/Reference and website :

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2010/exelon_hpc-cps-eng.php :

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/advisories-avis/prof/2010/exelon_hpc-cps-eng.pdf

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Division of Pharmacovigilance
and Pharmacoeconomics(DFP)