



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 0953/DAF/10  
Nº ref.

日期: 23/08/2010  
Data/Date:

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: 關於含entacapone藥物(Stalevo®, Comtan®)安全性的最新資訊

Ass./Subject: Latest safety update on medications containing entacapone(Stalevo®, Comtan®)

頁數: 1/2

Nº folhas/N. pages:

隨件附上一則關於含entacapone藥物(Stalevo®, Comtan®)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](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](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 medications containing entacapone(Stalevo®, Comtan®) 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](http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm)
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2<sup>nd</sup> 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](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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主題： 關於含entacapone藥物(Stalevo<sup>®</sup>, Comtan<sup>®</sup>)安全性的最新資訊

Subject : Latest safety update on medications containing entacapone(Stalevo<sup>®</sup>, Comtan<sup>®</sup>)

已知levodopa/carbidopa可引起高血壓和心悸等心血管系統方面的不良反應，近日多項臨床試驗的綜合分析(meta-analysis)指出，相對只服用levodopa/carbidopa的病人，服用Stalevo<sup>®</sup>(levodopa/carbidopa與entacapone的複方制劑)的帕金森病人有可能增加心肌梗塞及其他心血管事件(心臟病發、中風和心血管死亡)的風險。然而，由於這些臨床試驗的設計並非針對心血管安全性的評估，大部分的試驗期間過短且多數事件只發在某個試驗中，再者，大部分參加試驗的病人已有心血管方面的危險因子，因此美國食物及藥物管理局(USFDA)目前沒有確認上述結果。在得出進一步的結論前，USFDA提醒醫生及其他衛生專業人士，對於正在服用levodopa/carbidopa的病人，如需增加Comtan<sup>®</sup>(entacapone)，應：

- 遵照Stalevo<sup>®</sup>和Comtan<sup>®</sup>說明書上的資訊處方藥物。
- 對於已正在用levodopa/carbidopa的病人，如須加上entacapone，應先對他們進行常規的心血管系統評估。
- 告知病人該藥可能增加上述心血管事件發生的機會。

藥物監測暨管理處

It is known that levodopa/carbidopa may induce cardiovascular adverse reactions such as hypertension and palpitation. Recent findings from meta-analysis of several clinical trials indicated increased risk of myocardial infarctions and cardiovascular events (heart attack, stroke, and cardiovascular deaths) in Parkinson's Disease patients treated with Stalevo<sup>®</sup>(combination of levodopa/carbidopa and entacapone) compared to those receiving levodopa/carbidopa alone. United States Food and Drug Administration (USFDA) has not confirmed the above observation because none of these clinical trials was designed to evaluate cardiovascular safety and durations for most of these studies were too short. Besides, most of the patients under the trials had pre-existing cardiovascular risk factors. Lastly, many of these events occurred only in a one single trial. Therefore, while pending for further reviews on the above safety concern, USFDA would like the prescribers and healthcare professionals to be aware of the following advice when entacapone has to be added to those patients who are currently on levodopa/carbidopa :

- adhere to the recommendations as described on the prescribing information of Stalevo<sup>®</sup> and Comtan<sup>®</sup>.
- conduct regular cardiovascular evaluations on patients of whom entacapone is necessitated to be added to their existing levodopa/carbidopa therapy.
- remind your patients the above cardiovascular disease may occur.

Division of Pharmacovigilance  
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm223423.htm>

<http://www.fda.gov/Drugs/DrugSafety/ucm223060.htm>