



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olmesartan安全性的最新資訊

Ass./Subject: Latest safety update on olmesartan

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Nº folhas/N. pages:

隨件附上一則關於olmesartan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 olmesartan 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olmesartan安全性的最新資訊  
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美國食物及藥物管理局(USFDA)正評估兩項臨床試驗(ROADMAP和ORIENT), 數據顯示, 相對於使用安慰劑的病人,服用高血壓藥物olmesartan的第II型糖尿病患者,出現與心血管相關死亡的比率較高。因此, USFDA對醫生、藥劑師和其他衛生專業人士提供下列資訊:

- 到目前為止, 並未得出olmesartan會增加死亡風險的結論。
- 對於高血壓病人, 相信olmesartan的效益仍然高於其潛在的風險。
- 現有評估olmesartan及其他血管緊張素II受體阻斷劑的臨床試驗並沒有提及該等藥物會增加與心血管相關的死亡率。
- 醫生應按照藥物的說明書適當地處方olmesartan。

藥物監測暨管理處

United States Food and Drug Administration(USFDA) is evaluating data from two clinical trials(ROADMAP and ORIENT) in which patients with type 2 diabetes taking the blood pressure medication, olmesartan had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. Therefore, USFDA offers the following information for the physicians, pharmacists and other healthcare professionals:

- Until now, it has not been concluded that olmesartan increases the risk of death.
- It is believed the benefits of olmesartan in patients with high blood pressure continue to outweigh the potential risks.
- Other controlled clinical trials evaluating olmesartan and other angiotensin II receptor blockers have not suggested an increased risk of cardiovascular-related death.
- Physicians should follow the recommendations in the drug label when prescribing olmesartan.

Division of Pharmacovigilance  
and Pharmacoeconomics(DFF)

參考資料/Reference and website :

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm215249.htm>

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm215222.htm>