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澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

參照編號 0729/DAF/11
Nº ref.

日期: 16/06/2011
Data/Date:

由

De/From: 部門/Dept.: 藥物事務廳 Department of Pharmaceutical Affairs

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傳真機/Fax: (853)-28524016

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thalidomide和血管緊張素受體阻斷劑安全性的最新資訊

Ass./Subject: Latest safety updates on thalidomide and angiotensin receptor blockers (ARBs)

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Nº folhas/N.pages:

隨件附上兩則關於thalidomide和血管緊張素受體阻斷劑安全性的最新資訊，請各位參閱，如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

此外，各位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，亦可於非辦公時間致電63009255。

謹祝 台安!

Attached herewith are two latest safety updates on thalidomide and angiotensin receptor blockers (ARBs). If any kind of adverse reaction is suspected 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 call 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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Thalidomide與血栓性栓塞

Thalidomide 與其他藥物併用以治療多發性骨髓瘤，近期一項上市後的回顧性研究指出，接受thalidomide治療的病人除了出現已知的靜脈血栓性栓塞，出現動脈血栓性栓塞的風險也較高，包括心肌梗塞和腦血管事件。雖然使用thalidomide的病人出現動脈血栓性栓塞的機制並不清楚，但在治療首5個月的風險最高。基於上述原因，藥物監測暨管理處建議醫生、藥劑師及其他衛生專業人士：

1. 採取措施減少所有血栓性事件的危險因子，包括吸煙、高血壓以及高血脂。
2. 對於接受上述藥物治療的病人，特別具有上述危險因子的病人，醫生在謹慎評估後，應在病人接受治療的最少首5個月，採取預防血栓性栓塞的措施。
3. 謹慎併用可能增加血栓性風險的藥物，如紅血球生成素和荷爾蒙替代療法。

血管緊張素受體阻斷劑不會增加癌症出現的風險

爲了評估病人使用血管緊張素受體阻斷劑(ARBs)後出現癌症的通報個案，美國食物及藥物管理局(USFDA)對31項隨機臨床試驗進行綜合分析(meta-analysis)。結果顯示，沒有接受ARBs治療的病人患原發癌症的機率爲6%，而服用ARBs的病人則爲7.2%，兩者並不存在因癌症而死亡的統計學差異，沒有證據顯示服用ARBs的病人出現初發癌症、因癌症而死亡、乳癌、肺癌或前列腺癌的風險較高。

USFDA仍會繼續評估關於ARBs安全性的資訊，但相信該類藥物的效益高於其潛在風險。藥物監測暨管理處建議醫生應按說明書處方該類藥物，如病人出現任何不良反應，應向本處通報。

藥物監測暨管理處

Thalidomide and thromboembolism

Thalidomide is a drug used in multiple myeloma combined with other medicines. A recent review of the post marketing data showed that patients treated with thalidomide have an increased risk of arterial thromboembolism, including myocardial infarction and cerebrovascular events, in addition to the established risk of venous thromboembolism. The mechanisms of arterial thromboses in patients treated with thalidomide are unknown and the risk appears to be greatest during the first 5 months of therapy. In light of the above, Division of Pharmacovigilance and Pharmacoeconomics advises physicians, pharmacists and other health professionals:

1. take action to minimise all modifiable risk factors for thromboembolic events including smoking, hypertension and hyperlipidemia.
2. administer thromboprophylaxis for at least the first 5 months of treatment after a careful assessment, especially in patients with thrombotic risk factors mentioned above.
3. cautiously use concomitant agents that may increase the risk of thromboembolic events, such as erythropoietic agents and hormone replacement therapy.



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Angiotensin receptor blockers (ARBs) : No increase of risk of developing cancer

To further evaluate the reported link between use of ARBs and cancer, the United States Food and Drugs Administration (USFDA) conducted a trial-level meta-analysis of 31 randomized controlled clinical trials. The study reported the frequencies of new cancer occurrence to be 7.2% for patients receiving ARBs compared to 6.0% for those not receiving ARBs. No statistically difference in cancer deaths was noted. There is no evidence of an increased risk of incident cancer, cancer-related death, breast cancer, lung cancer, or prostate cancer in patients receiving ARBs.

USFDA is reviewing information related to this safety concern and believes the benefits of ARBs continue to outweigh their potential risks. Physicians are encouraged to prescribe ARBs according to the insert and report any adverse drug reactions to Division of Pharmacovigilance and Pharmacoeconomics.

Division of Pharmacovigilance
and Pharmacoeconomics(DFF)

參考資料/References and websites :

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsoonthesafetyofmedicines/CO N120200>

<http://www.fda.gov/Drugs/DrugSafety/ucm257516.htm>