



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

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主題: 關於非那雄胺(finasteride)和紅血球生成素(erythropoiesis-stimulating agents, ESAs)安全性的最新資訊

Ass./Subject: Latest safety updates on finasteride and erythropoiesis-stimulating agents(ESAs)

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星加坡藥監局(HSA)通知衛生專業人士以下兩則分別關於非那雄胺(finasteride)及紅血球生成素(erythropoiesis stimulating agents, ESAs)安全性的最新資訊,簡述如下:

● **Finasteride與潛在的男性乳癌風險**

2009年12月,英國藥物管理局(MHRA)完成了男性病人服用不同含量finasteride後乳癌風險的回顧性研究,得出的結論是不能排除男性病人服用fiasteride後發生乳癌的風險。數據指出,雖然相對於服用安慰劑的病人,服用finasteride 5mg的男性病人乳癌的整體發生率並不顯著增加,然而,數據顯示服用finasteride的病人具有較高乳癌發生率的趨勢;然而,並沒有服用finasteride 1mg的男性病人發生乳癌的個案。Finasteride增加乳癌風險的機制可能與其增加內源性睪酮,繼而增加雌二醇的水平有關。

對此,衛生專業人士應教育病人,若發現乳房組織出現任何改變,如腫塊、疼痛、男性女乳症或乳頭分泌時,應立即通知醫生。

● **紅血球生成素(erythropoietin stimulating agents, ESAs)的安全性**

i) 縮短腫瘤惡化的時間:一些研究指出,相對於服用安慰劑,接受ESA的癌症病人顯示出較高的死亡率或腫瘤惡化的時間縮短。試驗中某些使用ESA的病人血紅蛋白水平超過12g/dL,高於使用ESA所建議的水平(<12g/dL)。

ii) 心血管相關的不良事件:相對於接受ESA後血紅蛋白水平較低的病人,接受ESA後血紅蛋白水平較高的病人出現較多嚴重的心血管不良事件,如心臟衰竭、非致命性的心肌梗死和中風。

iii) 血管栓塞的不良事件:一項研究指出,相對於採取標準的血液保護措施,在進行脊髓外科手術前沒有接受預防血栓形成措施的病人,使用epoetin alfa的病人出現較多的深部靜脈栓塞和其他臨床相關的血管栓塞性不良事件。



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到目前為止，本廳並未接獲關於使用ESAs後發生腫瘤惡化或心血管/栓塞事件的本地通報個案，然而，基於本地亦可能會發生上述不良事件，建議衛生專業人士，就任何的適應症而需使用ESAs時，血紅蛋白的目標水平都不應超過12g/dL。

醫生、藥劑師或其他衛生專業人士如懷疑由非那雄胺(finasteride)、紅血球生成素(erythropoiesis-stimulating agents, ESAs)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 - 澳門士多鳥拜斯大馬路 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！

The Health Sciences Authority of Singapore(HSA) notified healthcare professionals about the two latest updates respectively on finasteride and erythropoiesis-stimulating agents(ESAs). Summaries are listed as follows:

- **Finasteride and potential risk of male breast cancer**

In December 2009, the UK MHRA completed a review on the risk of breast cancer in men taking different strengths of finasteride, and concluded that an increased risk of male breast cancer associated with finasteride use cannot be excluded. Data from studies of 5mg finasteride were reviewed, although the overall incidence of male breast cancer in patients who received 5mg finasteride was not significantly different compared to patients who received placebo, the data showed that there was a trend towards male breast cancer occurring more frequently in patients who had received finasteride. However, no cases of breast cancer were reported in men treated with 1mg finasteride.

Healthcare professionals are advised to inform their patients taking finasteride to promptly report any changes in their breast tissue such as lumps, pain, gynaecomastia or nipple discharge to their doctors.

- **Safety of erythropoietin stimulating agents(ESAs)**

i) Shorter time to tumour progression: Several studies conducted in cancer patients showed higher mortality or shorter time to tumour progression in patients randomized to receive an ESA as compared to placebo. In some of these trials, patients were treated with ESA to achieve haemoglobin levels > 12 g/dL. This level is higher than the recommended haemoglobin target level for ESA therapy, which is ≤ 12 g/dL.

ii) Cardiovascular-related adverse events: Patients who were randomised to receive an ESA to achieve higher haemoglobin levels experienced more serious adverse cardiovascular outcomes such as congestive heart failure, non-fatal myocardial infarction, non-fatal stroke as compared to those who received an ESA to achieve lower haemoglobin levels.



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- iii) Thrombovascular adverse events: A study documented a higher incidence of deep vein thrombosis and similar rates of other clinically relevant thrombovascular events with epoetin alfa versus standard of care for blood conservation in subjects who did not receive prophylactic anticoagulation before spinal surgery.

So far, there have been no local reports of ADR associated with tumour progression or cardiovascular/thrombotic events in cancer patients using ESAs. However, in view of the above, healthcare professionals are advised that the target haemoglobin level for all indications of ESAs should not exceed 12 g/dL.

If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of finasteride, Erythropoietin stimulating agents(ESAs) 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 of Department of Pharmaceutical Affairs

蔡炳祥
Choi Peng Cheong

參考資料/Reference and website :

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/product_safety_alerts/safety_alerts_2010/finasteride_and_potential.html

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/product_safety_alerts/safety_alerts_2010/erythropoietin_stimulating.html