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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

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由

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

簽署者/Ass./Signat.: 吳國良代廳長 Ng Kuok Leong – Acting Chief of DAF

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simvastatin、5- α 還原酶抑制劑和pioglitazone安全性的最新資訊

Ass./Subject: Latest safety updates on simvastatin, 5- α reductase inhibitors (5-ARIs) and pioglitazone

頁數: 1/3

Nº folhas/N. pages:

隨件附上三則關於simvastatin、5- α 還原酶抑制劑和pioglitazone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_wservlets_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

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 three latest safety updates on simvastatin, 5- α reductase inhibitors (5-ARIs) and pioglitazone. 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_wservlets_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!

藥物事務廳代廳長
Acting Chief of Department of Pharmaceutical Affairs


吳國良

Ng Kuok Leong



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Simvastatin與肌肉損傷

相對於服用較低劑量或其他同為他汀類(statins)藥物的病人，每天服用80mg simvastatin的病人出現肌病的風險較高，於治療的首年、與某些藥物併用或具有導致simvastatin較易引致肌病的基因的病人風險較高。80mg劑量的simvastatin降低低密度脂蛋白膽固醇(LDL-C)的效能只比40mg高6%，但引致肌肉損傷的風險高出10倍以上，因此，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. 只有當病人服用了12個月或更久而沒有出現肌肉毒性時，才可對病人繼續使用80mg的simvastatin。
2. 對病人不要首次便處方80mg的simvastatin。
3. 對於服用40mg simvastatin仍不能達到預期LDL-C指標的病人，應考慮其他可降低LDL-C的治療方案，以進一步降低病人的LDL-C。
4. 對於與simvastatin併用時可能增加肌肉損傷風險的藥物，可參考藥物說明書的建議，如病人需要服用與simvastatin產生相互作用的藥物時，可考慮改用其他潛在較少相互作用風險的statins類藥物。
5. 教導病人如出現肌肉疼痛、壓痛或虛弱、暗紅色尿液或不明的疲倦時，立即向醫生求診。

5- α 還原酶抑制劑與高階前列腺癌

兩項大規模的隨機控制試驗(RCTs)的回顧研究指出，雖然服用5mg finasteride和dutasteride(統稱為5- α 還原酶抑制劑)的病人出現低風險前列腺癌的機率較低，然而，其出現高階前列腺癌(high grade prostate cancer)的風險卻較高，因此，藥物監測暨管理處提醒醫生、藥劑師及其他衛生專業人士：

1. 5- α 還原酶抑制劑並未經美國食物及藥物管理局(USFDA)核准用於預防前列腺癌。
2. 注意5- α 還原酶抑制劑可增加高階前列腺癌的風險。
3. 於開始5- α 還原酶抑制劑治療前，應採取適當評估措施，排除包括與前列腺增生相似的前列腺癌在內的其他尿道疾病。
4. 留意開始5- α 還原酶抑制劑治療後，病人於6個月內前列腺特異抗原(PSA)將下降約50%，因此，如病人服用5- α 還原酶抑制劑後PSA增高，或即使在正常男性的PSA範圍內，可能是存在前列腺癌的徵兆，應對病人作評估。

Pioglitazone與膀胱腫瘤

近期一項在法國進行的回顧性隊列研究(cohort study)的結果指出，pioglitazone會增加膀胱腫瘤的風險，歐盟藥物管理局(EMA)轄下的人用藥物委員會(CHMP)正在評估所有相關數據，以決定對該藥原有效益和風險平衡的影響。

基於此，藥物監測暨管理處建議醫生、藥劑師及其他衛生專業人士監測使用pioglitazone治療的病人膀胱腫瘤的風險，待有進一步消息時，本處將作公佈。

藥物監測暨管理處



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Simvastatin and muscular damage

Patients taking simvastatin 80 mg daily have an increased risk of myopathy compared to patients taking lower doses of this drug or other drugs in the same class. This risk appears to be higher during the first year of treatment, is often the result of interactions with certain medicines, and is frequently associated with a genetic predisposition toward simvastatin-related myopathy. The 80-mg dose lowers the LDL cholesterol by an additional 6% over simvastatin 40 mg while the risk of muscular damage is 10 times higher. Therefore, Division of Pharmacovigilance and Pharmacoeconomics recommends physicians, pharmacists and other health professionals:

1. maintain patients on simvastatin 80 mg only if they have been taking this dose for 12 or more months without evidence of muscle toxicity.
2. not start new patients on simvastatin 80 mg.
3. place patients who do not meet their LDL cholesterol goal on simvastatin 40 mg on alternative LDL-C lowering treatment that provides greater LDL-C lowering.
4. follow the recommendations in the simvastatin-containing medicines labels regarding drugs that may increase the risk for muscle injury when used with simvastatin. Switch patients who need to be initiated on a drug that interacts with simvastatin to an alternative statin with less potential for the drug-drug interaction.
5. instruct patients to immediately contact their healthcare professional if they experience muscle pain, tenderness or weakness, dark or red colored urine, or unexplained tiredness.

5- α reductase inhibitors (5-ARIs) and high grade prostate cancer

Review of two large, randomized controlled trials (RCTs) demonstrated an overall reduction in lower risk forms of prostate cancer in patients with finasteride 5 mg and dutasteride (collectively called 5- α reductase inhibitors or 5-ARIs) treatment but showed an increased incidence of high grade prostate cancer. Therefore, Division of Pharmacovigilance and Pharmacoeconomics reminds physicians, pharmacists and other health professionals:

1. 5-ARIs are not approved by the United States Food and Drug Administration (USFDA) for the prevention of prostate cancer.
2. be aware that 5-ARIs may increase the risk of high-grade prostate cancer.
3. prior to initiating therapy with 5-ARIs, perform appropriate evaluation to rule out other urological conditions, including prostate cancer, that might mimic benign prostatic hyperplasia.
4. be aware that treatment with 5-ARIs causes an approximate 50% reduction in prostate-specific antigen (PSA) values by 6 months. Therefore, any confirmed increase in PSA while on a 5-ARI may signal the presence of prostate cancer and should be evaluated, even if that PSA is in the normal range of male.

Pioglitazone and bladder cancer

Results of a retrospective cohort study carried out in France which became available recently appear to suggest an increased risk of bladder cancer with pioglitazone. The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) is currently reviewing all relevant data to assess their impact on the balance of benefits and risks of these medicines.

In light of the above, Division of Pharmacovigilance and Pharmacoeconomics advise physicians, pharmacists and other health professionals to monitor the risk of bladder cancer in patients on pioglitazone treatment. We will make further announcements as soon as new information becomes available.

Division of Pharmacovigilance
and Pharmacoeconomics (DFF)

參考資料/References and websites :

<http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm>

http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2011/06/WC500107515.pdf

<http://www.fda.gov/Drugs/DrugSafety/ucm258314.htm>