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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

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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: 關於促性腺激素釋放激素安全性的最新資訊

Ass./Subject: Latest safety update on gonadotropin-releasing hormone(GnRH) agonists

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隨件附上一則關於促性腺激素釋放激素安全性的最新資訊, 請醫生、藥劑師及其他衛生專業人士參閱, 如台端懷疑由促性腺激素釋放激素(gonadotropin-releasing hormone(GnRH) agonists)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

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!

Attached herewith is the latest safety update on gonadotropin-releasing hormone(GnRH) agonists for your reference. If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of gonadotropin-releasing hormone(GnRH) agonists 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, Department of Pharmaceutical Affairs

蔡炳祥
Choi Peng Cheong



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主題：關於促性腺激素釋放激素安全性的最新資訊

Subject : Latest safety update on gonadotropin-releasing hormone(GnRH) agonists

美國食物及藥物管理局正評估使用促性腺激素釋放激素 (gonadotropin-releasing hormone(GnRH) agonists)治療的前列腺癌男性病人，其罹患糖尿病和某些心血管疾病(心臟病發、突然性心血管死亡、中風)的風險是否可能增加。USFDA正進行相關的回顧性研究，目前並未作出任何關於GnRH激動劑的結論，包括在使用這些藥物治療的前列腺癌病人中，是否增加糖尿病及心血管疾病的風險。現時，USFDA對衛生專業人士作出下列建議：

- 衛生專業人士應留意上述可能發生的安全性問題，當採取治療方案時，應謹慎衡量使用GnRH激動劑的效益和風險。
- 應對接受GnRH激動劑的病人作出監測，以確認有否罹患糖尿病和心血管疾病。
- 醫生應按照現行的臨床實踐準則，對病人作心血管危險因子的評估，包括吸烟以及血壓、膽固醇、血糖和體重的升高。
- 提醒病人除非醫生建議，否則不應停止GnRH激動劑的治療。

— The United States Food and Drug Administration(USFDA) is evaluating whether Gonadotropin-Releasing Hormone (GnRH) Agonists may increase the risk of diabetes and certain cardiovascular diseases (heart attack, sudden cardiac death, stroke) in men receiving these medications for the treatment of prostate cancer. USFDA's review is ongoing. The agency has not made any conclusions about GnRH agonists and whether they increase the risk of diabetes and cardiovascular disease in patients receiving these medications for prostate cancer. At this time, USFDA recommends healthcare professionals that:

- Healthcare professionals should be aware of these potential safety issues and carefully weigh the benefits and risks of GnRH agonists when determining treatment.
- Patients receiving GnRH agonists should be monitored for development of diabetes and cardiovascular disease.
- Physicians should manage cardiovascular risk factors for patients, such as smoking and increases in blood pressure, cholesterol, blood sugar, and weight, according to current clinical practice.
- Physicians should remind patients not to stop their treatment with GnRH agonists unless recommended by their attending physician.

參考資料/Reference and website :

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm210576.htm>

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm209842.htm>

藥物監測暨管理處
Division of Pharmacovigilance
and Pharmacoeconomics(DFF)