



The FDA Safety Information and Adverse Event Reporting Program

GnRH Agonists: Increased Risk of Diabetes and Cardiovascular Disease

[20/10/2010]

近日美國 FDA 發布有關治療前列腺癌藥品「性腺激素釋放素促進劑」(Gonadotropin-releasing hormone agonist, GnRH agonist)，以下簡稱 GnRH 促進劑」之藥品安全資訊。依據文獻發現，該類藥品可能會小幅增加病人糖尿病和某些心血管疾病(例如：心臟病發作、心臟猝死、中風)之風險，因此美國 FDA 要求該類藥品仿單加刊相關警語及注意事項。美國 FDA 同時提醒醫師應審慎評估病患之用藥風險，定期監控病人之血糖及/或糖化血紅素(HbA1c)以及心血管疾病之相關徵兆。

經查，衛生署核准 GnRH 促進劑類藥品包括：leuprolide (leuprorelin)、goserelin、triptorelin、nafarelin 及 buserelin 等成分(其許可證及適應症請參閱附件)。另查全國藥物不良反應通報資料，尚無疑似使用該類藥品引起糖尿病或心血管疾病之不良反應通報。除此之外，衛生署核准該類藥品仿單之「副作用」章節中也已刊載「...心臟血管系統：充血性心衰竭、周邊水腫、靜脈栓塞/靜脈炎、肺栓塞等...」。衛生署食品藥物管理局亦將儘速蒐集相關安全資訊，評估是否要求廠商修訂仿單內容。

衛生署曾於 98 年再評估該類藥品之風險與效益，並於 98 年 4 月 8 日公告該類藥品應於仿單之「不良反應」處，增加刊載有關腦下垂體中風(Pituitary apoplexy)之相關警語。衛生署食品藥物管理局並於 99 年 5 月 5 日發布新聞稿提醒醫師及民眾，該類藥品可能增加糖尿病和某些心血管疾病之風險。衛生署食品藥物管理局再次提醒醫師，處方該類藥品前，應謹慎評估其臨床效益及風險，同時嚴密監視病人不良反應之發生。病人倘若用藥期間有任何不適或疑問，應立即回診開立處方醫師，勿任意停藥。

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Audience: Oncology, Endocrine, Cardiovascular

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The U.S. Food and Drug Administration (FDA) has notified the manufacturers of the Gonadotropin-Releasing Hormone (GnRH) agonists of the need to add new safety information to the *Warnings and Precautions* section of the drug labels. This new information warns about increased risk of diabetes and certain cardiovascular diseases (heart attack, sudden cardiac death, stroke) in men receiving these medications for the treatment of prostate cancer. FDA's notification to manufacturers of GnRH agonists to add this safety information is based on the Agency's review of several published studies¹⁻⁷, described in the Agency's [Ongoing Safety Review of GnRH Agonists and possible increased risk of diabetes and certain cardiovascular diseases](#), issued in May 2010.

GnRH agonists are approved to treat the symptoms (palliative treatment) of advanced prostate cancer. The benefits of GnRH agonist use for earlier stages of prostate cancer that have not spread (non-metastatic prostate cancer) have not been established.

Although the risk for diabetes and cardiovascular diseases appears to be low in men receiving GnRH agonists for prostate cancer, it is important for healthcare professionals to evaluate patients for risk factors for these diseases. Healthcare professionals should always carefully weigh the benefits and risks of using GnRH agonists before determining appropriate treatment for prostate cancer.

Patients who are receiving treatment with GnRH agonists should undergo periodic monitoring of blood glucose and/or glycosylated hemoglobin (HbA1c). Increased blood glucose levels may represent development of diabetes or worsening of blood glucose control in patients with diabetes. Healthcare professionals should also monitor patients for signs and symptoms suggestive of development of cardiovascular disease and manage according to current clinical practice.