



The FDA Safety Information and  
Adverse Event Reporting Program

## Olmesartan: Drug Safety Communication –

### FDA Review Finds Cardiovascular Risks for Diabetics Not Conclusive

[Posted 06/24/2014]

FDA 已經完成了 Olmesartan 的安全性審查，並發現糖尿病患者使用此藥，**沒有**明顯證據顯示增加心血管風險。FDA 認為高血壓的患者使用 Olmesartan，依然是利多於風險。

#### 建議

患者不應自行停用 Olmesartan 和降血壓藥；FDA 對 Olmesartan 使用建議維持不變，但須將相關研究訊息加進仿單內。

[Posted 06/24/2014]

**AUDIENCE:** Cardiology, Pharmacy, Family Practice, Endocrinology

**ISSUE:** FDA has completed its safety review and has found no clear evidence of increased cardiovascular risks associated with use of the blood pressure medication olmesartan in diabetic patients. FDA believes the benefits of olmesartan in patients with high blood pressure continue to outweigh the potential risks.

**BACKGROUND:** FDA safety review was prompted by the results of the ROADMAP trial. The ROADMAP (Randomized Olmesartan and Diabetes Microalbuminuria Prevention) clinical trial examined the effects of olmesartan in patients with type 2 diabetes, to see whether olmesartan could delay kidney damage. There was an unexpected finding of increased risk of cardiovascular death in the olmesartan group compared to the group taking a placebo, or sugar pill. However, the risk of non-fatal heart attack was lower in the olmesartan-treated patients. To evaluate these findings, FDA reviewed additional studies, including a large study in Medicare patients.

**RECOMMENDATION:** Patients should not stop taking olmesartan or any blood pressure medication without first discussing it with their health care professional. Recommendations for use of olmesartan remain the same, but FDA will require information about some of the studies to be included in the drug labels.