



**The FDA Safety Information and
Adverse Event Reporting Program**

Aliskiren-containing Medications: Drug Safety Communication - New Warning and Contraindication

[Posted 04/20/2012]

美國FDA公告，將aliskiren與其他藥品如ACEIs、ARBs併用於糖尿病或腎功能不良的病患，會造成腎功能惡化、低血壓、高血鉀之風險。Aliskiren與ACEIs、ARBs禁止併用於糖尿病患者、中至重度腎功能不良的患者(GFR < 60 mL/min)。仿單將會根據臨床研究“ALTITUDE”更新仿單內容。

[Posted 04/20/2012]

AUDIENCE: Internal Medicine, Pharmacy, Endocrinology

ISSUE: FDA notified healthcare professionals of possible risks when using blood pressure medicines containing aliskiren with other drugs called angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) in patients with diabetes or kidney (renal) impairment. These drug combinations should not be used (are contraindicated) in patients with diabetes. In addition, avoid use of aliskiren with ARBs or ACEIs in patients with moderate to severe renal impairment (i.e., where glomerular filtration rate [GFR] < 60 mL/min). The labels for the aliskiren drugs are being updated based on preliminary data from a clinical trial, “Aliskiren Trial in Type 2 Diabetes Using Cardio-Renal Endpoints (ALTITUDE).”

BACKGROUND: Aliskiren is a renin inhibitor used to treat high blood pressure (hypertension) by lowering blood pressure.

RECOMMENDATION: Concomitant use of aliskiren with ARBs or ACEIs in patients with diabetes is contraindicated because of the risk of renal impairment, hypotension, and hyperkalemia. Avoid use of aliskiren with ARBs or ACEIs in patients with renal impairment where GFR < 60 mL/min. Patients should not stop taking aliskiren without talking to your healthcare professional. Stopping aliskiren suddenly can cause problems if your high blood pressure (hypertension) is not treated. See the Drug Safety Communication for the Data Summary, a list of ACEI and ARB products, and additional recommendations for healthcare professionals and patients.