MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Trilipix (fenofibric acid): Drug Safety Communication - Label Change

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FDA 公告降膽固醇藥物 fenofibric acid 可能不會降低心臟病發作或中風的危險，這是根據 ACCORD Lipid trial 的研究。ACCORD Lipid trial 實驗結果發現 fenofibrate 合併 simvastatin 與單用 simvastatin 的組別做比較，心臟方面副作用的風險沒有差異。藥品仿單的資訊將會依照 FDA 公告更新。

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AUDIENCE: Family Practice, Cardiology, Pharmacy

ISSUE: FDA notified healthcare professionals the cholesterol-lowering medicine Trilipix (fenofibric acid) may not lower a patient's risk of having a heart attack or stroke. FDA reviewed the data from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Lipid trial. The ACCORD Lipid trial found no significant difference in the risk of experiencing a major adverse cardiac event between the group treated with fenofibrate plus simvastatin compared with simvastatin alone.

Information from the trial has been added to the Important Limitations of Use and Warnings and Precautions sections of the Trilipix physician label and to the patient Medication Guide.

BACKGROUND: Trilipix (fenofibric acid) was approved by FDA in 2008 to treat cholesterol in the blood by lowering the total amount of triglycerides and low-density lipoprotein (LDL) cholesterol, and increasing the high-density lipoprotein (HDL) cholesterol.

RECOMMENDATION: Fenofibrate at a dose equivalent to 135 mg of Trilipix was not shown to reduce coronary heart disease morbidity and mortality in patients in two large randomized controlled trials of patients with type 2 diabetes mellitus; healthcare professionals should consider the benefits and risks of Trilipix when deciding to prescribe the drug to patients, and counsel patients about those benefits and risks.