MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Severe liver injury associated with the use of dronedarone (marketed as Multaq)

[01-14-2011]

美國 FDA 於 1 月 14 日發布有關含 dronedarone 成分藥品之用藥安全資訊，依據美國藥品不良反應通報資料，發現疑似使用含該成分藥品導致罕見嚴重肝臟傷害之不良反應案件，因此要求該藥品仿單加刊相關警語與副作用，同時將持續追蹤該藥品之安全性。

「脈泰克膜衣錠」，作為治療心律不整之用途，為 99 年 6 月核准之新藥，健保尚未給付，國內目前約一百多人使用該藥品。另查我國藥物不良反應通報資料，尚無疑似使用含該成分藥品導致不良反應之案件。

該藥品許可證持有廠商已向衛生署食品藥物管理局說明，將依美國 FDA 仿單修訂內容，進行仿單內容更新。衛生署食品藥物管理局將同時請醫療院所加強監控該藥品不良反應情形，並提醒正在使用該藥品之病患，勿擅自停藥，若有疑慮應立即詢問主治醫生。

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AUDIENCE：Cardiology, Gastroenterology

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ISSUE: FDA notified healthcare professionals and patients about cases of rare, but severe liver injury, including two cases of acute liver failure leading to liver transplant in patients treated with the heart medication dronedarone (Multaq). Information about the potential risk of liver injury from dronedarone is being added to the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections of the dronedarone labels.

BACKGROUND: Dronedarone is a drug used to treat abnormal heart rhythm in patients who have had an abnormal heart rhythm during the past six months. Dronedarone was approved with a Risk Evaluation and Mitigation Strategy (REMS) with a goal of preventing its use in patients with severe heart failure or who have recently been in the hospital for heart failure. In a study of patients with these conditions, patients given dronedarone had a greater than two-fold increase in risk of death.

RECOMMENDATION: Healthcare professionals were reminded to advise patients to contact a healthcare professional immediately if they experience signs and symptoms of hepatic injury or toxicity (anorexia, nausea, vomiting, fever, malaise, fatigue, right upper

quadrant pain, jaundice, dark urine, or itching) while taking dronedarone. Healthcare professionals should consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment. Additional information for Healthcare Professionals, for Patients and a Data Summary is provided in the Drug Safety Communication.