



The FDA Safety Information and Adverse Event Reporting Program

Mirapex (pramipexole): Drug Safety Communication - Ongoing Safety Review, Possible Risk of Heart Failure

[Posted 09/19/2012]

美國FDA提醒，Mirapex (pramipexole)有可能增加心衰竭的風險。然而相關研究有限制 (limitations)，所以FDA無法確定Mirapex (pramipexole)會增加心臟衰竭的風險。FDA將持續追蹤並隨時更新公告。

FDA評估臨床隨機試驗，結果使用Mirapex (pramipexole)的組別相較使用安慰劑，造成心衰竭的案例較多，但在統計學上沒有意義。另有兩篇流行病學研究，提出Mirapex (pramipexole)會增加心臟衰竭的風險，但研究有限制，使其難以確定研究結果是否有意義。

醫療人員可繼續依照藥品仿單建議，給予Mirapex (pramipexole)治療患者；患者勿隨意停藥，有任何問題應聯繫醫療人員。

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AUDIENCE: Neurology

ISSUE: FDA notified healthcare professionals about a possible increased risk of heart failure with Mirapex (pramipexole). Results of recent studies suggest a potential risk of heart failure that needs further review of available data. Because of the study limitations, FDA is not able to determine whether Mirapex increases the risk of heart failure. FDA is continuing to work with the manufacturer to clarify further the risk of heart failure with Mirapex and will update the public when more information is available.

FDA evaluated a pooled analysis of randomized clinical trials and found that heart failure was more frequent with Mirapex than with placebo; however, these results were not statistically significant. FDA also evaluated two epidemiologic studies that suggested an increased risk of new onset of heart failure with Mirapex use. However, study limitations make it difficult to determine whether excess heart failure was related to Mirapex use or other influencing factors.

BACKGROUND: Mirapex (pramipexole) is a prescription medicine used to treat the signs and symptoms of Parkinson's disease and moderate to severe symptoms of primary restless legs syndrome, in a class of medicines called dopamine agonists.

RECOMMENDATION: At this time, FDA has not concluded that Mirapex increases the risk of heart failure. Healthcare professionals should continue to follow the recommendations in the drug label when prescribing Mirapex. Patients should continue to take their Mirapex as directed and should contact their health care professional if they have any questions or concerns