

Potential Heart Failure Risk with Mirapex (pramipexole)

The FDA notified healthcare professionals on September 19, 2012 of possible increased risk of heart failure associated with the use of Mirapex (pramipexole) due to the results of a recent study. Mirapex is a dopamine agonist used to treat the signs and symptoms of Parkinson's disease and restless leg syndrome. The study that indicated increased risk of heart failure had several study limitations that requires the FDA to further investigate if Mirapex use was the cause or if it was related to other influencing factors. The FDA continues to work with the manufacturer of Mirapex and will update the public when more information is available.

Patients with heart failure can present with the following signs and symptoms: tachycardia, fatigue due to low cardiac output, and edema. Other warning signs are lack of appetite, nausea, confusion, impaired thinking, persistent coughing, and wheezing. Most patients who present with heart failure do so because of inability to provide adequate cardiac output. The cardinal symptom of left ventricular failure is breathlessness that may manifest with progressively increasing severity. Heart failure is the number one cause of hospitalization for Medicare patients and affects nearly 5.7 million Americans of all ages. Heart failure will continue to increase in prominence as a major health problem in the United States. Since, the FDA cannot conclude that Mirapex increases the risk of heart failure; patients should continue to take it as directed and be counseled to seek medical attention if they experience symptoms of heart failure. Please report any adverse effects or side effects related to the use of Mirapex to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

References:

- FDA Drug Safety Communication: Ongoing safety review of Parkinson's drug Mirapex (pramipexole) and possible risk of heart failure. FDA. Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm319779.htm#professionals> . Accessed: October 12, 2012.
- Dumitru I, Ooi, H. Heart Failure. EMedicine. Available at: <http://emedicine.medscape.com/article/163062-overview#a0101> . Accessed: October 12, 2012.
- American Heart Association. Heart Failure. Available at: http://www.heart.org/HEARTORG/Conditions/HeartFailure/Heart-Failure_UCM_002019_SubHomePage.jsp . Accessed: October 13, 2012.

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