MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Stalevo (entacapone/carbidopa/levodopa)

[03/31/2010]

美國FDA 近期發布有關巴金森氏症藥品Stalevo®（含entacapone、carbidopa及levodopa 三種成分之複方製劑）之安全資訊。依據一項臨床試驗結果，發現長期使用Stalevo® 藥品者，相較於長期使用含carbidopa 及levodopa 二種成分之複方製劑者，可能有較高之罹患前列腺癌之情形，但Stalevo® 與前列腺癌間之因果關係目前仍無法明確定論，尚須進一步評估。因此，美國FDA 提醒醫療人員應注意病患使用該藥品產生前列腺癌之可能，並呼籲病患不可擅自停藥。

Stalevo (entacapone/carbidopa/levodopa)

Audience: Neurology, Oncology, and Family Medicine

[Posted 03/31/2010]

FDA notified healthcare professionals and patients that it is evaluating data from a long-term clinical trial called Stalevo Reduction in Dyskinesia Evaluation - Parkinson's Disease (STRIDE-PD), that may suggest that patients taking Stalevo may be at an increased risk for developing prostate cancer. Other controlled clinical trials evaluating Stalevo or Comtan (entacapone) did not find an increased risk of prostate cancer. FDA is still reviewing the available information and has not concluded that Stalevo increases the risk of developing prostate cancer. Healthcare professionals should be aware of this possible risk and follow current guidelines for prostate cancer screening. FDA recommends that healthcare professionals follow the recommendations in the drug label when prescribing Stalevo and Comtan. Patients should not stop taking their medication unless directed to do so by their healthcare professional.