

### US FDA reviews safety of Stalevo

The US FDA has announced that it is reviewing the safety of Stalevo after data from the STRIDE-PD\* trial indicated that the Parkinson's disease medication may be associated with an increased risk of prostate cancer.

A greater number of patients receiving the fixed combination of levodopa/carbidopa/entacapone were observed to have prostate cancer compared with patients receiving levodopa/carbidopa [Sinemet]. Prostate cancer is commonly diagnosed in men of a similar age to those included in the STRIDE-PD trial. Previous clinical trials, of shorter duration, have not found any association between Stalevo and prostate cancer in patients with Parkinson's disease.

Entacapone is also sold as a single-ingredient drug, under the brandname Comtan.

\* Stalevo Reduction In Dyskinesia Evaluation – Parkinson's Disease

FDA. FDA Drug Safety communication: ongoing safety review of Stalevo (entacapone/carbidopa/levodopa) and possible development of prostate cancer. Internet Document : [2 pages], 31 Mar 2010. Available from: URL: <http://www.fda.gov>

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