US FDA announces ongoing assessment of CV risk for Stalevo

The US FDA is conducting an ongoing investigation of clinical trial data which suggest that Stalevo (carbidopa/levodopa/entacapone) use may be associated with an increased risk of cardiovascular (CV) events,* compared with Sinemet (carbidopa/levodopa) use.

The safety announcement states that patients should not stop taking Stalevo or Comtan (entacapone alone) unless advised by their healthcare professional. Such professionals should regularly evaluate the CV status of patients taking Stalevo, particularly if they have a history of CV disease. The FDA is to examine additional methods of assessing the CV safety of Stalevo, and will update the public when their review is finalised.

* myocardial infarction, stroke and CV death

See also Reactions 1297; p2; 801075618

FDA. FDA Drug Safety Communication: ongoing safety review of Stalevo and possible increased cardiovascular risk. Internet Document : [2 pages], 20 Aug 2010. Available from: URL: http://www.fda.gov 801140738