



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): carbidopa / entacapone / levodopa

Procedure No. EMEA/H/C/PSUSA/00000547/201810

Period covered by the PSUR: 18 October 2015 to 17 October 2018



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for carbidopa / entacapone / levodopa, the scientific conclusions of CHMP are as follows:

Dopamine dysregulation syndrome (DDS) is described as a compulsive pattern of dopaminergic misuse above doses adequate to control motor symptoms. Dopamine dysregulation syndrome is a well-recognised risk for dopaminergic medication used in Parkinson's disease. Dopamine dysregulation syndrome is mentioned in the product information of other dopaminergic medication used in Parkinson's disease such as levodopa/carbidopa, apomorphine, levodopa/benserazide, rotigotine and ropinirole. Dopamine dysregulation syndrome was included in five adverse drug reaction reports during this PSUR reporting period. Cumulatively, dopamine dysregulation syndrome has been included in 10 reports. As part of this PSUSA procedure, update of the levodopa/carbidopa/entacapone SmPCs with identical changes regarding dopamine dysregulation syndrome as agreed previously by the CMDh in the PSUSA process for levodopa/carbidopa containing products is considered warranted. The SmPC section 4.4 and 4.8 are being updated to add Dopamine Dysregulation Syndrome (DDS) with a frequency "not known" and to add further explanation with regards to DDS to section 4.8 to increase awareness and understanding on the pathology and add a warning to section 4.4 to recommend relevant precautions. The Package leaflet is updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for carbidopa / entacapone / levodopa the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing carbidopa / entacapone / levodopa is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.