



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): levodopa

Procedure No. EMEA/H/C/PSUSA/00107800/201912

Period covered by the PSUR: 21/12/2018 To: 20/12/2019



Scientific conclusions

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

In view of the available data on sensation of choking from spontaneous reports including 17 cases with a close temporal relationship, the PRAC considers a causal relationship between levodopa inhalation powder and sensation of choking is established. The PRAC concluded that the product information of products containing levodopa inhalation powder should be amended accordingly.

Update of section 4.8 of the SmPC to add the adverse reaction 'sensation of choking' with a frequency 'not known'. 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 levodopa the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing 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.