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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): mannitol (indicated in cystic fibrosis)

Procedure No. EMEA/H/C/PSUSA/00009226/201504

Period covered by the PSUR: 13 April 2014 to 12 April 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for MANNITOL, the scientific conclusions of CHMP are as follows:

One new signal has been investigated during the reporting interval as a result of two reports of patients not completing all BIDA (mannitol Initiation Dose Assessment) steps prior to continuing on mannitol therapy. In order to assess patients for bronchial hyperresponsiveness to inhaled mannitol, the patient must complete and pass the initiation dose assessment before initiating the treatment, which forms part of the risk minimisation educational materials. Hence, the PRAC considered that the product information should be updated to reflect that a full BIDA (mannitol Initiation Dose Assessment) dose must be administered prior to starting treatment in order to assess patients for bronchial hyper-responsiveness to inhaled mannitol.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing mannitol (indicated in cystic fibrosis) were warranted.

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 MANNITOL the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing MANNITOL is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.