11 December 2025
EMADOC-1700519818-2917355
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. PSUSA/00009226/202504

Period covered by the PSUR: 3 years to 12 April 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for mannitol (indicated in cystic fibrosis), the scientific conclusions of PRAC are as follows:

In view of available data on the risk of bronchospasm, haemoptysis and cough related sequelae and the hindsight gained over the last decade on the safety profile of mannitol (indicated in cystic fibrosis), and that the information contained in the additional risk minimisation measures (aRMM) are also reflected in the SmPC, the PRAC considered that the aRMM can be deleted from the Annex II.D. The PRAC concluded that the conditions of the marketing authorisations of products containing mannitol (indicated in cystic fibrosis) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for mannitol (indicated in cystic fibrosis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mannitol (indicated in cystic fibrosis) 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.