



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): sevelamer

Procedure No. EMEA/H/C/PSUSA/00002697/201810

Period covered by the PSUR: 31 October 2017 – 30 October 2018



### **Scientific conclusions**

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

During the period covered by this PSUR 14 case reports of gastrointestinal (GI) disorders associated with sevelamer crystals have been published, including one case of colonic/caecal mass formation.

Considering the seriousness of these events, the increasing number of well-documented and published reported cases, including the 4 cases with a positive dechallenge after discontinuation of sevelamer only, the risk of "sevelamer crystals associated with serious gastrointestinal disorders" should be updated in section 4.4 and should also be reflected in section 4.8 of the SmPC and in the corresponding sections of the package leaflet.

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 sevelamer the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sevelamer 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.