EMA/CHMP/768723/2014
Committee for Medicinal Products for Human Use (CHMP)

Renagel

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: sevelamer

Procedure No. EMEA/H/C/000254/PSUV/0101

Period covered by the PSUR: 01-May-2013 to 30-Apr-2014

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Scientific conclusions

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

The safety issue “acidosis” has been described in the literature for sevelamer hydrochloride (Renagel) during the review period. This safety concern is already listed as an important identified risk in the RMP and mentioned in section 4.4 of the SmPC and in the package leaflet (PL) for Renagel. However, this adverse event is not documented as an “Undesirable effect” in section 4.8 of the SmPC of Renagel.

The PRAC recommends that the adverse event “acidosis, increased serum chloride levels” should be listed as uncommon in section 4.8 of the SmPC and in the PL of sevelamer hydrochloride (Renagel).

Therefore, in view of available data regarding sevelamer hydrochloride and sevelamer carbonate, the PRAC considered that changes to the product information of sevelamer hydrochloride were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for sevelamer hydrochloride, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance sevelamer hydrochloride is favourable subject to the proposed changes to the product information.

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