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): pantoprazole

Procedure No. EMEA/H/C/PSUSA/00002285/201708

Period covered by the PSUR: 24 August 2012 to 23 August 2017

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Scientific conclusions

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

A cumulative search of the safety database for potential cases of paraesthesia using updated search criteria up to 31 January 2018 was performed. This yielded 711 case reports with 852 events. From the 711 cases, 131 cases were serious. 485 out of 711 cases were considered related to treatment with pantoprazole.

Positive de-challenge was recorded in 190 cases, 172 of which were considered related to pantoprazole (as determined by the company). The events in 28 of these 172 cases were serious. There were 44 cases of negative de-challenge overall, 25 of which were considered to be related to treatment with pantoprazole. Of these related cases, 8 were serious and 17 were classified as non-serious.

Due to the number of cases with a positive dechallenge paraesthesia, the product information of pantoprazole containing medicinal product should ensure that paraesthesia is added as an adverse drug reaction with unknown frequency in section 4.8 of the SmPC. The package leaflet should be updated accordingly, if applicable.

Cumulatively there have been 55 serious cases of hypocalcaemia of which a significant number were associated with the known side effect of hypomagnesaemia. Based on this information, "hypocalcaemia in association with hypomagnesaemia" should be included in section 4.8 of the SmPC of all pantoprazole-containing medicinal products. The package leaflet should be updated accordingly, if applicable.
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 pantoprazole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pantoprazole 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.