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): naloxegol

Procedure No. EMEA/H/C/PSUSA/00010317/201809

Period covered by the PSUR: 16.03.2018 – 15.09.2018

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Scientific conclusions

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

Cumulatively 8 reports of gastrointestinal perforation, 2 of which were fatal were reported on Naloxegol. There was no evidence that these patients suffered from terminal illness. In both of the fatal cases naloxegol was used despite the patient already being at risk of gastrointestinal perforation. As patients at risk of gastrointestinal perforation were excluded from clinical trials the role of naloxegol in contribution of these events cannot be excluded. The PRAC considers that the warning in section 4.4 and section 4.8 of the SmPC should be amended to reflect that cases of gastrointestinal perforation have been reported for naloxegol, some of which have been fatal. As information on Naloxegol in relation to this side effect is now available the class effect wording can hereby be replaced. Furthermore a reference to the existing contraindication on gastrointestinal obstruction should be added to 4.4 of the SmPC. As there exists sufficient plausibility based on the mechanism of action of Naloxegol 'GI perforation' should be added to 4.8 of the SmPC with a frequency "not known" and it should be reclassified as an important identified risk in the RMP for Moventig. The package leaflet should be updated accordingly.

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