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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): liraglutide

Procedure No. EMEA/H/C/PSUSA/00001892/201812

Period covered by the PSUR: 01/01/2018 to 31/12/2018

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Scientific conclusions

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

Data from clinical trials showed that liraglutide is associated with delayed gastric emptying. In the LEADER study, delayed gastric emptying was reported three times more frequently in the liraglutide group compared to the placebo group. As there is sufficient evidence to conclude on a causal relationship between delayed gastric emptying and liraglutide, delayed gastric emptying should be included as an ADR in section 4.8 of the SmPC with a frequency allocation of 'uncommon' and in section 4 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 liraglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing liraglutide 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.