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): insulin degludec / liraglutide

Procedure No. EMEA/H/C/PSUSA/00010272/201609

Period covered by the PSUR: 01-Apr-2016 - 30-Sep-2016

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Scientific conclusions

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

Based on the outcome of the LEADER study for liraglutide, the MAH proposed to update the product information by adding the adverse drug reactions (ADRs) 'cholecystitis' and 'cholelithiasis' with the frequency uncommon. Both 'cholecystitis' and 'cholelithiasis' are already included in other liraglutide-containing medicinal products' product information. The PRAC agreed with the MAH's proposal. The Package Leaflet is 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 insulin degludec / liraglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing insulin degludec / 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.