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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/00010272/201603

Period covered by the PSUR: 01 Oct 2015 - 31 March 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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:

A signal 'lipase increased' was presented by the MAH for the liraglutide component. Increases of lipase and amylase are reported in clinical trials of liraglutide and the combination insulin degludec/liraglutide. Updates of the product information regarding the increased enzymes were proposed by the MAH to sections 4.4 and 4.8.

The same signal has been reviewed in the liraglutide PSUR and the product information was updated. As the signal is based on essentially the same data, the liraglutide SmPC wording about increased lipase and increased amylase approved by the PRAC will have to be implemented for insulin degludec/liraglutide also.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing liraglutide, such as Insulin degludec/liraglutide, were warranted.

The PRAC, however, recommended no amendment of section 4.4. Addition of Increased lipase and Increased amylase to the table in section 4.8 of the SmPC as undesirable effects with System Organ Class ‘Investigation’ and frequency "common" was agreed. The Package leaflet is to 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 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.