EMA/396551/2019
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 aspart

Procedure No. EMEA/H/C/PSUSA/00001749/201809

Period covered by the PSUR: 01/10/2017 To: 30/09/2018

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Scientific conclusions

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

Based on the post-marketing data submitted within this PSUR, the PRAC concludes that anaphylactic reactions should be added to section 4.8 of the SmPC for Fiasp, in line with the SmPC for NovoRapid and NovoMix. Following 7 new reported cases of medically confirmed systemic allergic reactions for Fiasp and the already established evidence suggesting a causal relationship between insulin aspart and anaphylactic reactions, the updates to the section 4.8 of SmPC for Fiasp are justified.

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