EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
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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): icosapent ethyl

Procedure No. EMEA/H/C/PSUSA/00010922/202107

Period covered by the PSUR: 26/07/2020 To: 25/07/2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

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

In view of available data on pharyngeal swelling from the literature, including in 2 cases a close temporal relationship and a positive re-challenge, the PRAC considers a causal relationship between icosapent ethyl and pharyngeal swelling is at least a reasonable possibility. The PRAC concluded that the product information of products containing icosapent ethyl should be amended 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 icosapent ethyl the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing icosapent ethyl 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.