14 December 2023
EMA/CHMP/564966/2023
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): fenofibrate / pravastatin

Procedure No. EMEA/H/C/PSUSA/00001363/202304

Period covered by the PSUR:
14/04/2021 To: 14/04/2023

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on muscle rupture from the literature and spontaneous reports including in 62 cases a close temporal relationship, a positive de-challenge (14 cases) and/or re-challenge (2 cases) and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pravastatin and muscle rupture is at least a reasonable possibility. The PRAC concluded that the product information of products containing fenofibrate/pravastatin should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for fenofibrate / pravastatin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fenofibrate / pravastatin 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.