27 January 2022
EMA/233858/2022
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): sildenafil (indicated for pulmonary hypertension)

Procedure No. EMEA/H/C/PSUSA/00002700/202105

Period covered by the PSUR: 01/06/2018 To: 31/05/2021

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
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 sildenafil (indicated for pulmonary hypertension), the scientific conclusions of CHMP are as follows:

In view of available data on the DDI between sildenafil and Entresto (sacubitril/valsartan) from the literature including cases and in view of a plausible mechanism of action, the PRAC considers a causal relationship between concomitant use of sildenafil and Entresto (sacubitril/valsartan) and increase in hypotension is established. The PRAC concludes that the product information of products containing sildenafil 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 sildenafil (indicated for pulmonary hypertension) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sildenafil (indicated for pulmonary hypertension) 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.