EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2021
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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): ribavirin (oral formulations)

Procedure No. EMEA/H/C/PSUSA/00010007/202007

Period covered by the PSUR: 24 July 2017 to 24 July 2020

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Scientific conclusions

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

The current safety information presented in section 4.8 of the SmPC is mainly focused on the safety profile of ribavirin in combination with interferon-containing products, which is no longer the standard of care. In view of this and the available clinical data, the PRAC considered that a brief statement summarizing the most common adverse reactions associated with ribavirin in combination with direct antiviral agents should be added at the beginning of section 4.8. The following adverse reactions were included: anaemia, nausea, vomiting, asthenia, fatigue, insomnia, cough, dyspnoea, pruritus and rash.

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 ribavirin (oral formulations) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ribavirin (oral formulations) 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.