28 February 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): glecaprevir / pibrentasvir

Procedure No. EMEA/H/C/PSUSA/00010620/201807

Period covered by the PSUR: 26 January 2018 to 25 July 2018

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Scientific conclusions

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

The PRAC noted analyses of the post-marketing cases of pruritus in glecaprevir / pibrentasvir-treated patients showing that in 24 out of 553 reports, an alternative aetiology or a confounding factor could not be identified. In these 24 cases, the early time to onset of the event relative to glecaprevir / pibrentasvir treatment initiation, the event severity as described by the reporter, resolution of the event with discontinuation of treatment, and/or recurrence of the event with re-initiation of treatment, suggest a potential role of glecaprevir / pibrentasvir in these cases. Pruritus was also the most common reaction observed in subjects with severe renal impairment in clinical trials and was also observed in post-liver or -kidney transplant patients. Therefore the PRAC considers that Section 4.8 of the SmPC should be updated to include the ADR “Pruritus” in the tabulated summary of adverse reactions, under the SOC Skin and subcutaneous tissue disorders.

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 glecaprevir / pibrentasvir the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing glecaprevir / pibrentasvir 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.