EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): dasabuvir

Procedure No. EMEA/H/C/PSUSA/00010363/201801

Period covered by the PSUR: 15 January 2017 – 14 January 2018

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Scientific conclusions

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

Based on the review of data presented in this PSUSA, covering the period from 15 January 2017 to 14 January 2018, as well as cumulative data since the European birth date, the PRAC considers that the product information of medicinal products containing the active substance dasabuvir should be updated as follows: update of section 4.8 of the SmPC to add diarrhoea with a frequency very common, vomiting with a frequency common and dehydratation with a frequency uncommon as adverse reactions identified with Exviera in combination with ombitasvir/paritaprevir/ritonavir and ribavirin. The package leaflet is updated 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 dasabuvir the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dasabuvir 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.