



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2024
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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): voretigene neparvovec

Procedure No. EMEA/H/C/PSUSA/00010742/202307

Period covered by the PSUR:
24/07/2022 To: 23/07/2023



Scientific conclusions

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

In view of available data on chorioretinal atrophy, the PRAC concluded that the product information of products containing voretigene neparovec should be amended accordingly.

Update of section 4.8 of the SmPC to add the adverse reaction "chorioretinal atrophy" to the list of those related to voretigene neparovec with a frequency "not known", and additional details on chorioretinal atrophy in the Description of selected adverse reactions. The Package leaflet is updated 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 voretigene neparovec the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing voretigene neparovec 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.