EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2023
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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): cenegermin

Procedure No. EMEA/H/C/PSUSA/00010624/202207

Period covered by the PSUR: 5 July 2021 to 5 July 2022

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Scientific conclusions

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

In view of the possible causal relationships between administration of the product and 34 cases of "corneal deposit", the following changes to the product information of medicinal products containing cenegermin are recommended (new text **underlined and in bold**, deleted text ~~strike through~~):

- Section 4.8

The following adverse drug reactions should be added under the SOC Eye disorders with a frequency common:

corneal deposit

The package leaflet will be 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 cenegermin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cenegermin 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.