



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2023
EMA/67676/2023
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): inotersen

Procedure No. EMEA/H/C/PSUSA/00010697/202207

Period covered by the PSUR: 05 July 2021 To: 05 July 2022



Scientific conclusions

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

In view of available data on thrombocytopenia with prolonged latency from spontaneous reports, the PRAC Rapporteur concluded that the product information of products containing inotersen should be amended accordingly.

In view of available data on glomerulonephritis from clinical trials and post-marketing, the PRAC Rapporteur concluded that the product information of products containing inotersen should be amended 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 inotersen the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing inotersen 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.