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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): inotersen

Procedure No. EMEA/H/C/PSUSA/00010697/202101

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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 liver transplant rejection from spontaneous reports, including in some cases a close temporal relationship, and the literature, the PRAC Rapporteur considers that monitoring of liver function tests in patients with a liver transplant should be at monthly intervals. 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.