



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/732027/2022
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): riluzole

Procedure No. EMEA/H/C/PSUSA/00002645/202112

Period covered by the PSUR: 12 December 2019 To: 12 December 2021



Scientific conclusions

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

In view of available data on rash from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC concluded that a causal relationship between riluzole and rash is at least a reasonable possibility and the product information of products containing riluzole 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 riluzole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing riluzole 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.