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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): nusinersen

Procedure No. EMEA/H/C/PSUSA/00010595/201811

Period covered by the PSUR: 30 May 2018 to 30 November 2018

Scientific conclusions

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

As of 19 October 2018, 100 AEs of hypersensitivity due to the administration of nusinersen were identified from the clinical trial database. Ninety-eight of these were considered not or unlikely related to nusinersen. The remaining 2 events (rash and eosinophil count increased, both nonserious) were possibly related to nusinersen. A cumulative search of postmarketing data identified 37 possible hypersensitivity events; 20 medically confirmed. Time to onset was reported in 11 of these 20, and ranged from directly following the injection to 1 week after the injection. Two events, angioedema and serum sickness, were considered serious and related. There were no reports of a patient discontinuing treatment due to these events. Taken together, there is sufficient evidence to support a causal association between nusinersen administration and hypersensitivity; and the PI should be updated accordingly. Prevention and treatment will be managed by routine clinical practice and no additional risk minimization measures or evaluations are required as part of the pharmacovigilance plan.

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 nusinersen the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nusinersen 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.