



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 April 2020  
EMA/332573/2020  
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): pitolisant

Procedure No. EMEA/H/C/PSUSA/00010490/201909

Period covered by the PSUR: From: 30/09/2018 To: 30/09/2020



## **Scientific conclusions**

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

A signal of suicidal ideation was reviewed by the MAH, with a total of 18 cases identified. Based on the evaluation of received cases with at least a reasonable possibility of a causal relationship with pitolisant, suicidal ideation is added as a new adverse drug reaction in the Product Information.

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