



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 September 2013  
EMA/CHMP/563242/2013  
Committee for Medicinal Products for Human Use

## Ranexa

### **Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation**

**International non-proprietary name::** Ranolazine

**Procedure No.:** EMEA/H/C/805/PSUV/0043

**Period covered by the PSUR:** 27.01.2012 to 26.01.2013



### **Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR for Ranexa, the scientific conclusions of PRAC are as follows:

A cumulative review of "myasthenic syndrome" was requested following the assessment of Ranexa PSUR 7. In PSUR 8, the MAH has provided the requested review. In clinical trials data, "myasthenic syndrome" was not described as treatment emergent adverse event, and the number of cases observed was not presented. In postmarketing data, although only one case with "myasthenic syndrome" has been reported, cases suggestive of "myasthenic syndrome" with positive dechallenge have been reported. Following the review of the information provided the PRAC concluded that there is no sufficient data supporting inclusion of "myasthenic syndrome" in section 4.8 of the SmPC. Inclusion of "muscular weakness" in section 4.8 of the SmPC was considered by the PRAC acceptable with the frequency "uncommon". In order to monitor the potential safety issue of "myasthenic syndrome" it was proposed to add this safety topic as a potential risk in the next update of the RMP.

The CHMP agrees with the scientific conclusions made by the PRAC.

### **Grounds recommending the variation to the terms of the Marketing Authorisation**

On the basis of the scientific conclusions for Ranexa the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance ranolazine is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.