20 November 2014

EMA/CHMP/793857/2014
Committee for Medicinal Products for Human Use (CHMP)

Sancuso

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

International non-proprietary name: granisetron

Procedure No.: EMEA/H/C/002296/PSUV/0034

Period covered by the PSUR: 20 October 2013 – 19 April 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
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Scientific conclusions

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

A review of all case reports which contained ADR terms related to either application site reaction or hypersensitivity/allergic type reaction have identified 65 cases that were attributed to probable hypersensitivity reactions. Of these 65 cases, there were 20 cases of Probable Hypersensitivity (Type I or Allergic Dermatitis), 23 of Probable Irritant Dermatitis, and 19 Not identified (possibly Allergy or possibly Irritant Dermatitis). Additionally 3 cases are noted which do not fall into any of the 3 categories. Based on this data the PRAC concluded that hypersensitivity reactions should be included in the product information.

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 Sancuso, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance granisetron is favourable subject to the proposed changes to the product information.

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

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