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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/0030

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Scientific conclusions

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

The PRAC considered that even if no cases of 'serotonin syndrome' have been reported to date in the global safety database for Sancuso, a mechanistic plausibility for the occurrence of serotonin syndrome exists, when 5-HT3 antagonist antiemetics are administered in combination with other serotonergic agents. The systemic availability of serotonin may be increased with the use of 5-HT3 antagonists which may lead to the stimulation of other serotonin receptor subtypes by endogenous serotonin. The PRAC, hence, concluded that there is a potential for developing Serotonin Syndrome with the 5-HT3 antagonist drug-class when used alone but mostly with other serotonergic drugs and therefore this information should be reflected in the product information of the class.

This class effect is already labelled in some other 5-HT3 antagonists and it is recommended that this class warning should also be included in the EU Product information for Sancuso.

Therefore, in view of available data regarding serotonin syndrome, the PRAC considered that changes to the product information were warranted.

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.