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Committee for Medicinal Products for Human Use (CHMP)

Aloxi

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

International non-proprietary name: palonosetron

Procedure No. EMEA/H/C/000563/PSUV/0033

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Scientific conclusions

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

The PRAC considers that the potential for serotonin syndrome across the class of 5-HT3 antagonists exists. A mechanistic plausibility for serotonin syndrome to occur 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. This is a labelled effect for some other 5-HT3 antagonists and it is recommended that wording about this class effect should be included in the EU SmPC.

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

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