EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2016
EMA/CHMP/131135/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Palonosetron Hospira

palonosetron

On 25 February 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Palonosetron Hospira, intended for the prevention of nausea and vomiting associated with cancer chemotherapy. The applicant for this medicinal product is Hospira UK Limited.

Palonosetron Hospira will be available as a solution for injection (250 microgram in 5 ml). The active substance of Palonosetron Hospira is palonosetron (as hydrochloride), an antiemetic and antinauseant agent belonging to the class of serotonin (5-HT3) antagonists (ATC code: A04AA05). It acts by blocking serotonin receptors and subsequently the neuronal cascade of events leading to nausea and vomiting caused by cancer chemotherapeutic agents.

Palonosetron Hospira is a generic of Aloxi, which has been authorised in the EU since 22 March 2005. Studies have demonstrated the satisfactory quality of Palonosetron Hospira. Since Palonosetron Hospira is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Aloxi was not required. A question and answer document on generic medicines can be found here.

The full indication is:

"Palonosetron Hospira is indicated in adults for:

- the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy,
- the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

Palonosetron Hospira is indicated in paediatric patients 1 month of age and older for:

- the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy."

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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It is proposed that Palonosetron Hospira be administered by a healthcare professional under appropriate medical supervision.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.