HAUTE AUTORITÉ DE SANTÉ

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

ALOXI (palonosetron), injectable antiemetic

No clinical benefit demonstrated in the prevention of nausea and vomiting caused by cancer chemotherapy in children aged ≥ 1 month by comparison with ondansetron.

Main points

- ALOXI 250 µg now has Marketing Authorisation in paediatric patients 1 month of age and older for the prevention of acute nausea and vomiting associated with highly or moderately emetogenic cancer chemotherapy.
- It is the first setron to have been granted Marketing Authorisation in infants aged between 1 and 6 months. Other setrons are used in this age group, but off-label. There are only very limited clinical data in children under 2 years of age, particularly in infants aged between 1 and 6 months.

Pre-existing indications[i]

- ALOXI already has Marketing Authorisation in this indication in adults.

Therapeutic use

- A number of drugs may be used in children, normally in combination: serotonin (5-HT_3) receptor antagonists (setrons), corticosteroids (dexamethasone) and NK1 receptor antagonists (aprepitant). However, no setron has been granted Marketing Authorisation in France in the prevention of nausea and vomiting caused by cancer chemotherapy in children under 6 months of age.
- **Role of the medicinal product in the therapeutic strategy**
  In children 1 month of age and older, ALOXI 250 µg, given intravenously, is a first-line antiemetic for the prevention of acute nausea and vomiting caused by moderately or highly emetogenic cancer chemotherapy. It is an alternative to other serotonin (5-HT_3) receptor antagonists ("setrons").

Clinical data

In the prevention of nausea and vomiting caused by cancer chemotherapy in paediatric cancer patients, 20 µg/kg palonosetron as a single IV infusion was non-inferior to 0.15 mg/kg ondansetron IV three times daily in terms of complete response (absence of vomiting, retching, or use of a rescue drug) according to the results of a comparative, randomised study during the first 24 hours after administration of a cycle of moderately or highly emetogenic cancer chemotherapy. There are still only limited clinical data on setrons in children under 2 years of age.

Special prescribing conditions

- Medicine for hospital prescription only.
- ALOXI must only be given before cancer chemotherapy.

[i] This summary does not cover this indication

Benefit of the medicinal product

- The actual benefit* of ALOXI 250 µg is substantial.
- ALOXI 250 µg does not provide clinical added value** (CAV V) by comparison with intravenous ondansetron.
- Recommends inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 03 February 2016 (CT-14842) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.
** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".