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EPAR summary for the public

Aloxi

palonosetron

This is a summary of the European public assessment report (EPAR) for Aloxi. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Aloxi.

What is Aloxi?

Aloxi is a medicine that contains the active substance palonosetron. It is available as a solution for injection (250 micrograms in 5 ml) and as capsules (500 micrograms).

What is Aloxi used for?

Aloxi is used to prevent nausea (feeling sick) and vomiting caused by chemotherapy (medicines to treat cancer). The solution for injection is used in adults and children 1 month of age or older for chemotherapy with medicines that are either a strong trigger of nausea and vomiting (such as cisplatin) or a moderate trigger (such as cyclophosphamide, doxorubicin or carboplatin). The capsules are only used in adults for chemotherapy that is a moderate trigger of nausea and vomiting in adults.

The medicine can only be obtained with a prescription.

How is Aloxi used?

Aloxi should only be given before chemotherapy. The solution for injection should be given by a healthcare professional about 30 minutes before the start of chemotherapy. In adults, the solution should be injected into a vein over 30 seconds at a dose of 250 micrograms. It may be made more effective by the addition of a corticosteroid (a type of medicine that can be used to prevent nausea and vomiting). In children, the solution should be given by infusion (drip) into a vein over 15 minutes at a dose of 20 micrograms per kilogram body weight.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

In adults, if the capsules are used, the patient should take one capsule one hour before the start of chemotherapy.

For more information, see the package leaflet.

How does Aloxi work?

The active substance in Aloxi, palonosetron, is a '$5HT_3$ antagonist'. This means that it stops a chemical in the body called 5-hydroxytryptamine (5HT, also known as serotonin) from attaching to 5HT3 receptors in the gut. When 5HT attaches to these receptors, it normally causes nausea and vomiting. By blocking these receptors, Aloxi prevents the nausea and vomiting that often happen after chemotherapy.

How has Aloxi been studied?

Aloxi solution for injection has been studied in three main studies involving 1,842 adults receiving chemotherapy that was a strong or a moderate trigger of nausea and vomiting. Aloxi, given at two different doses, was compared with ondansetron and dolasetron (other medicines of the same type).

Aloxi solution for injection has also been investigated in one study involving 502 children receiving chemotherapy that was a strong or a moderate trigger of nausea and vomiting, where Aloxi was compared with ondansetron.

A further study compared three doses of Aloxi capsules (250, 500 and 750 micrograms) with the solution for injection in 651 adults receiving chemotherapy that was a moderate trigger of nausea and vomiting.

All of the studies measured the number of patients who did not vomit after receiving chemotherapy.

What benefit has Aloxi shown during the studies?

Aloxi solution for injection was as effective as the comparator medicines. With chemotherapy that was a strong trigger of nausea and vomiting, 59% of the adults receiving Aloxi did not vomit in the 24 hours after chemotherapy (132 out of 223), compared with 57% of the patients receiving ondansetron (126 out of 221). With chemotherapy that was a moderate trigger of nausea and vomiting, 81% of the adults receiving Aloxi did not vomit in the 24 hours after chemotherapy (153 out of 189) compared with 69% of those receiving ondansetron (127 out of 185). When it was compared with dolasetron, these values were 63% for Aloxi (119 patients out of 189) and 53% for dolasetron (101 patients out of 191).

In the study in children receiving chemotherapy that was a strong or moderate trigger of nausea and vomiting, 59% of the children receiving Aloxi solution for injection at a dose of 20 micrograms/kilogram did not vomit in the 24 hours after chemotherapy (98 out of 165), which was the same percentage as seen in patients receiving ondansetron (95 out of 162).

In the study looking at Aloxi capsules, all three doses of Aloxi were as effective as the solution for injection over 24 hours, with around three-quarters of the patients not vomiting. However, only the 500 microgram dose remained as effective as the solution for injection over the first five days after chemotherapy: around 59% of the patients receiving the 500 microgram capsule or the injection did not vomit during this period.

What is the risk associated with Aloxi?

The most common side effect with Aloxi (seen in between 1 and 10 patients in 100) is headache. With the solution for injection, dizziness, constipation and diarrhoea are also seen in between 1 and 10 adults in 100. For the full list of all side effects and restrictions with Aloxi, see the package leaflet.

Why has Aloxi been approved?

The CHMP decided that the benefits of Aloxi are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Aloxi?

A risk management plan has been developed to ensure that Aloxi is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Aloxi, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Aloxi

The European Commission granted a marketing authorisation valid throughout the European Union for Aloxi on 22 March 2005.

The full EPAR for Aloxi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Aloxi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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