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EPAR summary for the public

Palonosetron Hospira

palonosetron

This is a summary of the European public assessment report (EPAR) for Palonosetron Hospira. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Palonosetron Hospira.

For practical information about using Palonosetron Hospira, patients should read the package leaflet or contact their doctor or pharmacist.

What is Palonosetron Hospira and what is it used for?

Palonosetron Hospira is used to prevent nausea (feeling sick) and vomiting caused by chemotherapy (medicines to treat cancer). It 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).

Palonosetron Hospira is a 'generic medicine'. This means that Palonosetron Hospira is similar to a 'reference medicine' already authorised in the European Union (EU) called Aloxi. For more information on generic medicines, see the question-and-answer document here.

Palonosetron Hospira contains the active substance palonosetron.

How is Palonosetron Hospira used?

Palonosetron Hospira should only be given before chemotherapy and can only be obtained with a prescription. It is available as a solution for injection which should be given by a healthcare professional about 30 minutes before the start of chemotherapy. In adults, the recommended dose is 250 micrograms, injected into a vein over 30 seconds. It may be given with a corticosteroid (another type of medicine that can be used to prevent nausea and vomiting) to increase the effect. In children,

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the solution should be given by infusion (drip) into a vein over 15 minutes at a dose of 20 micrograms per kilogram body weight.

How does Palonosetron Hospira work?

The active substance in Palonosetron Hospira, palonosetron, is a '5HT3 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, Palonosetron Hospira prevents the nausea and vomiting that often happen after chemotherapy.

How has Palonosetron Hospira been studied?

The company provided data from the published literature on palonosetron. No additional studies were needed as Palonosetron Hospira is a generic medicine that is given by injection and contains the same active substance as the reference medicine, Aloxi.

What are the benefits and risks of Palonosetron Hospira?

Because Palonosetron Hospira is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Palonosetron Hospira approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Palonosetron Hospira has been shown to be comparable to Aloxi. Therefore, the CHMP's view was that, as for Aloxi, the benefit outweighs the identified risk. The Committee recommended that Palonosetron Hospira be approved for use in the EU.

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

A risk management plan has been developed to ensure that Palonosetron Hospira 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 Palonosetron Hospira, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Palonosetron Hospira

The European Commission granted a marketing authorisation valid throughout the European Union for Palonosetron Hospira on 8 April 2016.

The full EPAR for Palonosetron Hospira 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 Palonosetron Hospira, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 04-2016