LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Palonosetron Reig Jofre (palonosetron)

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Summary Public Assessment Report

Palonosetron Reig Jofre

(palonosetron)

250 micrograms solution for injection

This is a summary of the public assessment report (PAR) for Palonosetron Reig Jofre. It explains how Palonosetron Reig Jofre was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Palonosetron Reig Jofre.

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

What is Palonosetron Reig Jofre and what is it used for?

Palonosetron Reig Jofre is a 'generic medicine'. This means that Palonosetron Reig Jofre is similar to a 'reference medicine' already authorised in the European Union (EU) called Aloxi.

Palonosetron Reig Jofre is used for the prevention of nausea and vomiting associated with cancer chemotherapy in adult, adolescents and children over one month of age.

How does Palonosetron Reig Jofre work?

Palonosetron Reig Jofre belongs to a group of medicines known as serotonin antagonists. These have the ability to block the action of the chemical, serotonin, which can cause nausea and vomiting.

How is Palonosetron Reig Jofre used?

The pharmaceutical form of Palonosetron Reig Jofre is solution for injection for intravenous injection.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Palonosetron Reig Jofre have been shown in studies?

No additional studies were needed as Palonosetron Reig Jofre is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Aloxi.

What are the possible side effects of Palonosetron Reig Jofre?

Because Palonosetron Reig Jofre is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Palonosetron Reig Jofre approved?

It was concluded that, in accordance with EU requirements, Palonosetron Reig Jofre has been shown to have comparable quality and to be similar to the reference medicine Aloxi. Therefore, the Medical Products Agency in Sweden decided that, as for Aloxi, the benefits are greater than its risks and recommended that it can be approved for use.

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

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Palonosetron Reig Jofre

The marketing authorisation for Palonosetron Reig Jofre was granted on 2016-06-22 in Sweden.

The full PAR for Palonosetron Reig Jofre can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Palonosetron Reig Jofre, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-07.