LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

FERANT
(palonosetron hydrochloride)

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Summary Public Assessment Report

Ferant
(palonosetron)

250 micrograms solution for injection

This is a summary of the public assessment report (PAR) for Ferant. It explains how Ferant 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 Ferant.

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

What is Ferant and what is it used for?

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

Ferant is used for the prevention of nausea and vomiting associated with cancer chemotherapy in adults, adolescents and in children over one month of age.

How does Ferant work?

Ferant 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 Ferant used?

The pharmaceutical form of Ferant 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 Ferant have been shown in studies?

No additional studies were needed as Ferant 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 Ferant?

Because Ferant 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 Ferant approved?

It was concluded that, in accordance with EU requirements, Ferant 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 Ferant?

A risk management plan has been developed to ensure that Ferant 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 Ferant, 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 Ferant

The marketing authorisation for Ferant was granted on 2016-07-14 in Sweden.

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

This summary was last updated in 2016-07.