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Akynzeo (*netupitant or fosnetupitant / palonosetron hydrochloride*)

An overview of Akynzeo and why it is authorised in the EU

What is Akynzeo and what is it used for?

Akynzeo is a medicine used to prevent nausea (feeling sick) and vomiting in adults with cancer who are receiving chemotherapy (medicines to treat cancer).

Some chemotherapy is known to induce severe nausea and vomiting, and Akynzeo is used in patients receiving either highly emetogenic (vomit-inducing) chemotherapy containing the cancer medicine cisplatin, or other chemotherapies that are moderately emetogenic.

Akynzeo is available as capsules and as a powder to be made up into a solution for injection. It contains the active substances netupitant and palonosetron (capsules) or fosnetupitant and palonosetron (powder).

How is Akynzeo used?

The recommended dose is one capsule taken by mouth one hour before starting chemotherapy or one injection given into a vein over 30 minutes before each chemotherapy cycle.

The medicine can only be obtained with a prescription. For more information about using Akynzeo, see the package leaflet or contact your doctor or pharmacist.

How does Akynzeo work?

The active substances in Akynzeo work by blocking two different mechanisms involved in inducing nausea and vomiting during chemotherapy. Palonosetron blocks $5HT_3$ receptors in the gut, which are responsible for the immediate phase of nausea (that occurs within the first 24 hours). Netupitant works by blocking neurokinin-1 (NK1)-receptors, which are found in the nervous system and are responsible for the delayed phase of nausea and vomiting (that occurs after the first 24 hours). Fosnetupitant is a 'prodrug' of netupitant, meaning that it is converted into the active substance netupitant in the body.

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By having palonsetron and netupitant or fosnetupitant together, Akynzeo helps provide control for both the immediate and delayed phases of nausea and vomiting than occur following chemotherapy.

Palonosetron, has been authorised on its own in the EU since 2005.

What benefits of Akynzeo have been shown in studies?

In a main study comparing Akynzeo with palonosetron alone, 90% of patients taking Akynzeo (121 out of 135) experienced no vomiting within 5 days of starting highly emetogenic chemotherapy compared with 77% of patients taking palonosetron alone (104 out of 136).

A second main study looked at the benefits of Akynzeo in patients undergoing moderately emetogenic chemotherapy. Around 88% of patients taking Akynzeo experienced no vomiting on day 1 following the first chemotherapy cycle, compared with 85% of patients taking palonosetron. The figures for day 2 to day 5 were 77% for patients in the Akynzeo group and 70% for those in the palonosetron group. This study involved 1,455 patients and the patients took dexamethasone, another medicine used to prevent vomiting, as an additional treatment.

What are the risks associated with Akynzeo?

The most common side effects with Akynzeo (which may affect up to 1 in 10 people) are headache, constipation and fatigue. For the full list of side effects and restrictions, see the package leaflet.

Why is Akynzeo authorised in the EU?

The European Medicines Agency noted that Akynzeo was effective at preventing both the immediate and delayed phases of nausea and vomiting following chemotherapy, and that the medicine has a favourable safety profile. The Agency therefore concluded that the medicine's benefits are greater than its risk and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Akynzeo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Akynzeo are continuously monitored. Side effects reported with Akynzeo are carefully evaluated and any necessary action taken to protect patients.

Other information about Akynzeo

Akynzeo received a marketing authorisation valid throughout the EU on 27 May 2015.

More information on Akynzeo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/akynzeo

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