



26 March 2015
EMA/CHMP/169908/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Akynzeo

netupitant / palonosetron

On 26 March 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Akynzeo, indicated for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

The applicant for this medicinal product is Helsinn Birex Pharmaceuticals Ltd.

Akynzeo (an antiemetic and antinauseant, ATC code A04) will be available as a 300 mg / 0.50 mg hard capsule. The active substances of Akynzeo (in a fixed dose combination) are netupitant and palonosetron. Netupitant is a selective antagonist of human substance P/neurokinin 1 (NK₁) receptors. Palonosetron is a 5-HT₃ receptor antagonist. 5-HT₃ receptors have been demonstrated to selectively stimulate the emetic response.

Delayed emesis has been largely associated with the activation of tachykinin family neurokinin 1 (NK₁) receptors (broadly distributed in the central and peripheral nervous systems) by substance P.

The benefit with Akynzeo is its ability to prevent acute and delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy. The addition of netupitant to palonosetron leads to an increased therapeutic activity of this fixed dose combination particularly in the delayed phase of emesis. Simplification of therapy by decreasing the number of individual dose units to be taken by the patient may furthermore improve patient compliance.

The most common side effects are headache, constipation and fatigue.

The full indication is: "Akynzeo is indicated in adults for the:

- Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



- Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.”

It is proposed that Akynzeo be subject to medical prescription. Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.