

Akynzeo[®] (fosnetupitant/palonosetron) – New formulation

- On April 20, 2018, [Helsinn announced](#) the FDA approval of [Akynzeo \(fosnetupitant/palonosetron\)](#) injection, in combination with [dexamethasone](#) in adults for the prevention of acute and delayed nausea and vomiting (N/V) associated with initial and repeat courses of highly emetogenic cancer chemotherapy.
 - Akynzeo for injection has not been studied for the prevention of N/V associated with anthracycline plus cyclophosphamide chemotherapy.
- Akynzeo is also available as oral capsules indicated in combination with dexamethasone in adults for the prevention of acute and delayed N/V associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.
- Akynzeo for injection contains palonosetron and fosnetupitant, a prodrug of netupitant. Palonosetron prevents N/V during the acute phase and fosnetupitant prevents N/V during both the acute and delayed phase after cancer chemotherapy.
- The bioequivalence of Akynzeo for injection with the oral formulation of netupitant was demonstrated, and the safety of Akynzeo for injection was established through a repeated dose safety study in cancer patients. No anaphylactic and injection site reactions related to Akynzeo for injection were reported in the study.
- Similar to Akynzeo capsules, the warnings and precautions of Akynzeo for injection include hypersensitivity and serotonin syndrome.
- The safety profile of Akynzeo for injection was generally similar to that seen with Akynzeo capsules. The most common adverse reactions ($\geq 3\%$) with Akynzeo capsule use were headache, asthenia, dyspepsia, fatigue, constipation, and erythema.
- The recommended dose of Akynzeo for injection is one vial infused intravenously 30 minutes before chemotherapy on day 1.
 - Dexamethasone 12 mg should be administered 30 minutes before chemotherapy on day 1. Then, dexamethasone 8 mg should be administered once daily on days 2 to 4.
- Helsinn plans to launch Akynzeo for injection in May 2018. Akynzeo for injection will be available as a lyophilized powder in a single-dose vial containing 235 mg fosnetupitant and 0.25 mg palonosetron for reconstitution.