

Cinvanti™ (aprepitant) – New drug approval

- On November 9, 2017, [Heron Therapeutics announced](#) the FDA approval of [Cinvanti \(aprepitant\)](#) for use in combination with other antiemetic agents in adults for the prevention of: acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose [cisplatin](#), and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
 - Cinvanti has not been studied for the treatment of established nausea and vomiting.
- Cinvanti is a substance P/neurokinin-1 (NK₁) receptor antagonist and the only polysorbate 80-free, intravenous (IV) formulation of an NK₁ receptor antagonist indicated for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV).
 - Aprepitant is also available as an [oral suspension](#) under the brand name, Emend®, and generically as [capsules](#).
 - Brand Emend (fosaprepitant) is also available as an [injection](#), which contains the prodrug of aprepitant. Emend injection contains polysorbate 80 in its formulation.
- Cinvanti was approved based on data demonstrating bioequivalence to Emend injection, supporting Cinvanti's efficacy for the prevention of acute and delayed CINV following HEC and MEC.
 - In addition, results from two pivotal crossover bioequivalence studies showed subjects receiving Cinvanti reported fewer adverse events vs. Emend injection, including fewer infusion-site reactions.
- Cinvanti is contraindicated in patients taking [pimozide](#) and in patients who are hypersensitive to any component of this product.
- Warning and precautions of Cinvanti include clinically significant CYP3A4 drug interactions, hypersensitivity reactions, decrease in INR with concomitant [warfarin](#), and risk of reduced efficacy of hormonal contraceptives.
- The most common adverse reactions (≥ 2%) with single-dose Cinvanti use were headache and fatigue.
- Cinvanti is given IV 30 minutes prior to chemotherapy on day 1. In HEC, the recommended dosage of Cinvanti is 130 mg, and in MEC the recommended dosage is 100 mg.
 - Cinvanti should be given in combination with other antiemetic agents, such as [dexamethasone](#) and a 5HT₃ antagonist.
 - Refer to the Cinvanti drug label for additional dosing details.
- Heron Therapeutics plans to launch Cinvanti in January 2018. Cinvanti will be available in single-dose vials as a 130 mg/18 mL injectable emulsion.