CINVANTI™ (aprepitant) injectable emulsion

Distribution Reference Guide

CINVANTI is an intravenously administered polysorbate 80-free neurokinin-1(NK_1) receptor antagonist approved for the prevention of both acute and delayed CINV.[1]

Supplied and marketed by: Heron Therapeutics, Inc.

Product name: CINVANTI

Established name: (aprepitant) injectable emulsion

CINVANTI pricing is based on wholesale acquisition cost (WAC). WAC is subject to change without notice. WAC is the list price to wholesalers for CINVANTI, without taking into account any terms specific to wholesalers, such as prompt payment terms, introductory launch terms, other discounts, or chargebacks.

Distributor Name	Website	Phone
Oncology Practices:		
• Cardinal Health Specialty Pharmaceutical Distribution	http://specialtyonline.cardinalhealth.com	1-866-677-4844
• McKesson Specialty	https://mscs.mckesson.com	1-800-482-6700
• Oncology Supply	www.oncologysupply.com	1-800-633-7555
Hospitals:		
• AmerisourceBergen Drug Corp.	www.amerisourcebergendrug.com	1-844-222-2273
• Cardinal Health	www.cardinalhealth.com	1-800-926-3161
• McKesson Corp. Pharmaceutical Division	https://connect.mckesson.com	1-855-625-6285

To help support the traditional claims processing timeline of newly approved products, ask your preferred distributor about extending dating terms.

INDICATION

CINVANTI is a substance P/neurokinin-1 (NK_1) receptor antagonist, indicated in adults, in combination with other antiemetic agents, 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).

Limitations of Use: CINVANTI has not been studied for treatment of established nausea and vomiting.

IMPORTANT SAFETY INFORMATION

Contraindications

CINVANTI is contraindicated in patients with hypersensitivity to any of the components of CINVANTI.

Concurrent use of pimozide with CINVANTI is contraindicated.

Warnings and Precautions

Clinically Significant CYP3A4 Drug Interactions

Aprepitant is a substrate, weak-to-moderate (dose-dependent) inhibitor, and an inducer of CYP3A4.

- Use with other drugs that are CYP3A4 substrates may result in increased plasma concentration of the concomitant drug.
  - Use of pimozide with CINVANTI is contraindicated due to the risk of significantly increased plasma concentrations of pimozide, potentially resulting in prolongation of the QT interval, a known adverse reaction of pimozide.
- Use of CINVANTI with strong or moderate CYP3A4 inhibitors (e.g., ketoconazole, diltiazem) may increase plasma concentrations of aprepitant and result in an increased risk of adverse reactions related to CINVANTI.
- Use of CINVANTI with strong CYP3A4 inducers (e.g., rifampin) may result in a reduction in aprepitant plasma concentrations and decreased efficacy of aprepitant.

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis and anaphylactic shock, have been reported with fosaprepitant, a prodrug of aprepitant, and with oral aprepitant. Symptoms including flushing, erythema, dyspnea, hypotension and syncope have been reported. If symptoms occur, discontinue CINVANTI. Do not reinstate if symptoms occur with first time use.

Decrease in INR with Concomitant Warfarin

Co-administration of CINVANTI with warfarin, a CYP2C9 substrate, may result in a clinically significant decrease in the International Normalized Ratio (INR) of prothrombin time. Monitor the INR in patients on chronic warfarin therapy in the 2-week period, particularly at 7 to 10 days, following initiation of CINVANTI with each chemotherapy cycle.

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information.

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Package Information: CINVANTI

Product code	Description	Dimensions	
NDC 47426-201-01 For payers requiring physicians to report 11-digit NDCs when reporting a drug on a claim form, please use the 11-digit code below: **NDC 47426-0201-01**	**Carton containing 1 single-dose glass vial of 130 mg aprepitant/18 mL**	Weight	0.0625 lbs
		Depth	1.786″
		Height	2.590″
		Width	1.411″
		Volume (cube)	6.527 in^3

Storage and Handling

Store CINVANTI in the refrigerator at 2°C to 8°C (36°F to 46°F).

CINVANTI can remain at room temperature for up to a maximum of 60 days.

The diluted drug solution is stable at ambient room temperature for 6 hours in 0.9% Sodium Chloride Injection, USP or 12 hours in 5% Dextrose Injection, USP.

Do not freeze.[1]

Heron Connect™

A fully integrated reimbursement and patient support program that provides practices with a dedicated team of Reimbursement Counselors available at **1-844-HERON11 (1-844-437-6611)** from 8 AM to 8 PM ET, Monday through Friday.

Drug Replacement

In the event that CINVANTI arrives damaged, is otherwise determined to be unfit for patient use,* or has expired, Heron Therapeutics will credit your practice for the purchase price of the product.

– Contact Heron Connect at **1-844-HERON11 (1-844-437-6611)** from 8 AM to 8 PM ET, Monday through Friday

Heron Commitment Program™†

The Heron Commitment Program™‡ credits the practice for the cost of CINVANTI§ in the event of a qualifying claim denial,† when program requirements are met.

*Determination will be made by the manufacturer of CINVANTI.

†A qualifying claim denial can be reviewed for the Heron Commitment Program™ when, for a patient covered under commercial insurance, the following criteria have been met, and documentation confirms: (a) the verification of benefits, conducted by the provider and/or Heron Connect™, meets all of the payer criteria and/or policy requirements, (b) the submitted claim for the Heron product is denied, and (c) the claim has been denied again by the commercial payer after the first level of appeals process has been followed.

‡The Heron Commitment Program™ and the other product support programs offered by Heron Therapeutics do not impose any purchase obligation at any time or in any manner. Use of CINVANTI may be discontinued at any time without penalty.

§Credits to your practice are processed by Heron Therapeutics.

IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions (cont'd)

Risk of Reduced Efficacy of Hormonal Contraceptives

The efficacy of hormonal contraceptives may be reduced during administration of and for 28 days following the last dose of CINVANTI. Advise patients to use effective alternative or back-up methods of non-hormonal contraception during treatment with CINVANTI and for 1 month following administration of CINVANTI or oral aprepitant, whichever is administered last.

Use in Specific Populations

Avoid use of CINVANTI in pregnant women as alcohol is an inactive ingredient for CINVANTI. There is no safe level of alcohol exposure in pregnancy.

Adverse Reactions

The most common adverse reactions with the 3-day oral aprepitant regimen in conjunction with MEC (≥1% and greater than standard therapy) were fatigue and eructation.

The most common adverse reactions with the single-dose intravenous fosaprepitant regimen in conjunction with HEC were generally similar to that seen in prior HEC studies with oral aprepitant. In addition, infusion site reactions (3%) occurred.

The most common adverse reactions with single-dose CINVANTI (≥2%) were headache and fatigue.

Please see Indication and additional Important Safety Information on reverse side and accompanying full Prescribing Information.

Reference: 1. CINVANTI [package insert]. Heron Therapeutics, Inc., San Diego, CA; November 2017.

If you have any distribution-related questions, please contact your account manager or call Heron Connect™ at **1-844-HERON11 (1-844-437-6611)** from 8 AM to 8 PM ET, Monday through Friday. You can also visit **cinvanti.com**.

www.cinvanti.com

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