FOCINVEZ™
(fosaprepitant injection)

Now Available

The first and only presentation of fosaprepitant that is:

- a ready-to-use IV solution, without the need for dilution or reconstitution[1,2]
- administered directly from the vial using included vial hanger[1]
- free of polysorbate 80[1]
- shelf stable for up to 90 days at room temperature[1]*
- covered by the Amneal PATHways® Patient Support Program

Now available from most major wholesaler and distributor partners

FOCINVEZ™ is available as follows:

Unit of Sale[1]	Unit of Sale Quantity[1]	NDC[1]	List (WAC)†
150 mg/50 mL (3 mg/mL)	Single-dose vial	70121-2631-1	$457.50
HCPCS Code[3]	**Descriptor**		
J1434	Injection, fosaprepitant (focinvez), 1 mg		

IMPORTANT SAFETY INFORMATION

INDICATIONS

FOCINVEZ™ is a substance P/neurokinin-1 (NK1) receptor antagonist indicated in adults and pediatric patients 6 months of age and older, 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.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

Limitations of Use:

FOCINVEZ™ has not been studied for the treatment of established nausea and vomiting.

CONTRAINDICATIONS

- FOCINVEZ™ is contraindicated in patients who are hypersensitive to any component of the product.
- Concurrent use of FOCINVEZ™ with pimozide is contraindicated.

Please see next page for additional Important Safety Information and visit Focinvez.us for full Prescribing Information.

*FOCINVEZ™ vials, when kept in original carton, can remain at 20°C to 25°C (68°F to 77°F) for up to 90 days, or refrigerated at 2°C to 8°C (36°F to 46°F) until expiration.[1]

† WAC as of 05/24/2024.

HCPCS, Healthcare Common Procedure Coding System; IV, intravenous; NDC, National Drug Code; WAC, wholesale acquisition cost.

References: 1. Focinvez. Prescribing information. Amneal Pharmaceuticals LLC; 2023. **2.** US Food and Drug Administration. Orange book: Approved drug products with therapeutic equivalence evaluations. Accessed May 1, 2024. https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm. **3.** CMS. Second quarter, 2024 HCPCS quarterly update. Updated April 17, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update.

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FOCINVEZ™ STORAGE & HANDLING

Ready-to-use formulation makes prep more efficient

For adult patients: Simply separate the vial hanger from the label and hang the single-dose vial of FOCINVEZ™ from an IV pole.[1]

For pediatric patients: Please refer to the full Prescribing Information for appropriate pediatric dosing and administration information.[1]

No reconstitution: Save time and resources without the need for diluent[1]
No dilution: Presented at the ready-to-use concentration of 3 mg/mL[1]
No refrigeration: Stable for storage at room temperature for up to 90 days[1]*

Amneal PATHways® Patient Access To Health

1-866-4AMNEAL (426-6325)

Amneal is pleased to offer reimbursement access and patient support services through the PATHways program.

PATHways Patient Access Specialists are available to assist healthcare providers and patients with:

- Benefit investigation
- Prior authorization support
- Affordability options like co-pay savings
- Claims assistance

Call toll-free Monday through Friday, 8 AM to 8 PM ET.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Clinically Significant CYP3A4 Interactions: Fosaprepitant, a prodrug of aprepitant, is a weak inhibitor of CYP3A4, and aprepitant is a substrate, inhibitor, and inducer of CYP3A4. See full Prescribing Information for recommendations regarding contraindications, risk of adverse reactions, and dosage adjustment of FOCINVEZ™ and concomitant drugs.

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis and anaphylactic shock, during or soon after infusion of fosaprepitant have occurred. Monitor patients during and after infusion. If hypersensitivity reactions occur, discontinue the infusion and administer appropriate medical therapy. Do not reinitiate FOCINVEZ™ in patients who experienced these symptoms with previous use.

Infusion Site Reactions: Infusion site reactions (ISRs), including thrombophlebitis and vasculitis, have been reported with the use of intravenous fosaprepitant. The majority of severe ISRs were reported with concomitant vesicant (anthracycline-based) chemotherapy administration. Avoid infusion into small veins. Discontinue infusion and administer treatment if a severe reaction develops.

Warfarin: Coadministration of fosaprepitant 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 FOCINVEZ™ with each chemotherapy cycle.

Hormonal Contraceptives: The efficacy of hormonal contraceptives may be reduced during treatment with FOCINVEZ™ and for 1 month following administration of the last dose of either fosaprepitant or oral aprepitant. Advise patients to use effective alternative or back-up methods of contraception.

ADVERSE DRUG REACTIONS

The most common adverse drug reactions in adults (≥2%) treated with FOCINVEZ™ are neutropenia, leukopenia, peripheral neuropathy, anemia, fatigue, diarrhea, asthenia, dyspepsia, urinary tract infection, pain in extremity.

Adverse reactions in pediatric patients treated with FOCINVEZ™ are similar to adults.

DRUG INTERACTIONS

Co-administration of FOCINVEZ™ with drugs that are inhibitors or inducers of CYP3A4 may result in increased or decreased plasma concentrations of aprepitant.

See full Prescribing Information for a list of clinically significant drug interactions.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are insufficient data on the use of fosaprepitant in pregnant women to identify a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
Lactation: There are no data on the presence of aprepitant in human breast milk.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Biosciences, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Visit Focinvez.us for full Prescribing Information.

Order from your wholesaler or contact Amneal: Toll Free 866.525.7270 | CustomerRelations@amneal.com

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IV, intravenous.

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