NAVITRUX™
(fosaprepitant) for injection

AVYXA

Ordering Information

To order NAVITRUX (fosaprepitant) for injection, please contact one of the authorized specialty distributors below:

150 mg per vial
NDC: 83831-0153-05

Institutions/Hospitals	150 mg per vial
ASD Healthcare (Cencora)	10312138
Cardinal Health Specialty	6152359
McKesson Plasma & Biologics	3109626
Physician Offices	**150 mg per vial**
BioCare	1003465
Cardinal Health Specialty	6152359
McKesson Specialty	5023432
Oncology Supply (Cencora)	10312128

Highlights[1]

- Supplied as lyophilized powder in a single-dose vial
- Reconstitute with 5 mL of 0.9% sodium chloride
- Add to infusion bag containing 145 mL of 0.9% sodium chloride to yield a final concentration of 1 mg/mL
- Reconstituted NAVITRUX and diluted solutions are stable for 24 hours at ambient room temperature at or below 25°C (77°F)

J-CODE

J3490

Unique J-Code Expected January 2027

Please see Important Safety Information on page 2-3 and full Prescribing Information for NAVITRUX.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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INDICATIONS

NAVITRUX™, in combination with other antiemetic agents, is indicated in adults and pediatric patients 6 months of age and older 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

- NAVITRUX has not been studied for the treatment of established nausea and vomiting.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NAVITRUX is contraindicated in patients:

- who are hypersensitive to any component of the product. Hypersensitivity reactions including anaphylactic reactions, flushing, erythema, and dyspnea have been reported.
- taking pimozide. Inhibition of CYP3A4 by aprepitant, the active moiety, could result in elevated plasma concentrations of this drug, which is a CYP3A4 substrate, potentially causing serious or life-threatening reactions, such as QT prolongation, a known adverse reaction of pimozide.

WARNINGS AND PRECAUTIONS

Clinically Significant CYP3A4 Drug Interactions

Fosaprepitant, a prodrug of aprepitant, is a weak inhibitor of CYP3A4, and aprepitant is a substrate, inhibitor, and inducer of CYP3A4.

- Use of NAVITRUX with other drugs that are CYP3A4 substrates, may result in increased plasma concentration of the concomitant drug.
  - Use of pimozide with NAVITRUX 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 NAVITRUX 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 NAVITRUX.
- Use of NAVITRUX with strong CYP3A4 inducers (e.g., rifampin) may result in a reduction in aprepitant plasma concentrations and decreased efficacy of NAVITRUX.

See full Prescribing Information for recommendations regarding contraindications, risk of adverse reactions, and dosage adjustment of NAVITRUX and concomitant drugs.

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis and anaphylactic shock, during or soon after infusion of fosaprepitant have occurred. Symptoms including flushing, erythema, dyspnea, hypotension and syncope have been reported.

Monitor patients during and after infusion. If hypersensitivity reactions occur, discontinue the infusion and administer appropriate medical therapy. Do not reinitiate NAVITRUX in patients who experience these symptoms with previous use.

Infusion Site Reactions

Infusion site reactions (ISRs) have been reported with the use of intravenous fosaprepitant. The majority of severe ISRs, including thrombophlebitis and vasculitis, were reported with concomitant vesicant (anthracycline-based) chemotherapy administration, particularly when associated with extravasation. Necrosis was also reported in some patients with concomitant vesicant chemotherapy. Most ISRs occurred with the first, second or third exposure to single doses of fosaprepitant and in some cases, reactions persisted for two weeks or longer. Treatment of severe ISRs consisted of medical, and in some cases surgical, intervention.

Avoid infusion of NAVITRUX into small veins or through a butterfly catheter. If a severe ISR develops during infusion, discontinue the infusion and administer appropriate medical treatment.

Decrease in INR with Concomitant 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 to10 days, following initiation of NAVITRUX with each chemotherapy cycle.

Please see Important Safety Information on page 2-3 and full Prescribing Information for NAVITRUX.

IMPORTANT SAFETY INFORMATION (continued)

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Risk of Reduced Efficacy of Hormonal Contraceptives

Upon coadministration with fosaprepitant, the efficacy of hormonal contraceptives may be reduced during administration of and for 28 days following the last dose of fosaprepitant. Advise patients to use effective alternative or back-up methods of contraception during treatment with NAVITRUX and for 1 month following the last dose of NAVITRUX or oral aprepitant.

ADVERSE REACTIONS

Most common adverse reactions in adults (≥2%) are: fatigue, diarrhea, neutropenia, asthenia, anemia, peripheral neuropathy, leukopenia, dyspepsia, urinary tract infection, pain in extremity.

Adverse reactions in pediatrics are similar to adults.

DRUG INTERACTIONS

See full Prescribing Information for recommendations regarding contraindications, risk of adverse reactions, and dosage adjustment of NAVITRUX and concomitant drugs.

USE IN SPECIFIC POPULATIONS

Lactation

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NAVITRUX and any potential adverse effects on the breastfed infant from NAVITRUX or from the underlying maternal condition.

Females and Males of Reproductive Potential

Contraception

Upon administration of NAVITRUX, the efficacy of hormonal contraceptives may be reduced. Advise females of reproductive potential using hormonal contraceptives to use an effective alternative or back-up non-hormonal contraceptive (such as condoms and spermicides) during treatment with NAVITRUX and for 1 month following the last dose of NAVITRUX or oral aprepitant.

Pediatric Use

Adverse reactions were similar to those reported in adult patients.

The safety and effectiveness of NAVITRUX for the prevention of nausea and vomiting associated with HEC or MEC have not been established in patients less than 6 months of age.

Patients with Hepatic Impairment

The pharmacokinetics of aprepitant in patients with mild and moderate hepatic impairment were similar to those of healthy subjects with normal hepatic function. No dosage adjustment is necessary for patients with mild to moderate hepatic impairment (Child-Pugh score 5 to 9). Because there are no clinical or pharmacokinetic data in patients with severe hepatic impairment (Child-Pugh score greater than 9), additional monitoring for adverse reactions in these patients may be warranted when NAVITRUX is administered.

OVERDOSAGE

There is no specific information on the treatment of overdosage with fosaprepitant or aprepitant.

In the event of overdose, NAVITRUX should be discontinued and general supportive treatment and monitoring should be provided.

Aprepitant is not removed by hemodialysis.

DOSAGE AND ADMINISTRATION GUIDELINES

It is very important that the dosage, preparation and administration instructions provided in the full prescribing information are strictly followed to reduce the risk of severe adverse reactions.

Do not mix or reconstitute NAVITRUX with solutions for which physical and chemical compatibility have not been established. NAVITRUX is incompatible with any solutions containing divalent cations (e.g., Ca^{2+}, Mg^{2+}), including Lactated Ringer's Solution and Hartmann's Solution.

Please see full Prescribing Information of NAVITRUX.

To report SUSPECTED ADVERSE REACTIONS, contact AVYXA Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Reference: 1. AVYXA Pharma, LLC. NAVITRUX (fosaprepitant) for injection. Prescribing information. Revised 06/2026.

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AVYXA Pharma, LLC offers resources to help your patients start and stay on prescribed therapy. We are dedicated to providing your patients with ongoing support to help them access AVYXA Pharma, LLC medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

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