FOSAPREPITANT 150MG VIAL FOR INJECTION (Low EDTA)

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Fosaprepitant for injection, in combination with other antiemetic agents, is indicated 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. • delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
2	Dosage	What is the recommended dosage?	Recommended Dosage: • Adults: 150 mg on Day 1. • Administer fosaprepitant for injection on Day 1 as an intravenous infusion over 20 to 30 minutes (adults), completing the infusion approximately 30 minutes prior to chemotherapy. See Full Prescribing Information for dosages of concomitant antiemetic(s).
3	Administration	How Fosaprepitant injection is administered?	Fosaprepitant for injection will be given on Day 1 of chemotherapy treatment. It will be given to you by intravenous (IV) infusion in your vein about 50 to 60 minutes before the start of chemotherapy treatment.
4	Administration	Use in Paediatric Population	The safety and effectiveness of fosaprepitant dimeglumine for the prevention of nausea and vomiting associated with HEC or MEC have not been established in patients less than 6 months of age. Pediatric use information is approved for Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.'s Emend (fosaprepitant) for injection. However, due to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.'s marketing exclusivity rights, this drug product is not labeled with that paediatric information.
5	Administration	Use in Geriatric Population	Other reported clinical experience with fosaprepitant has not identified differences in responses between elderly and younger patients. In general, use caution when dosing elderly patients as they have a greater frequency of decreased hepatic, renal or cardiac function and concomitant disease or other drug therapy.
6	Side Effects	What are the most common side effects?	Most common adverse reactions were fatigue, diarrhea, neutropenia, asthenia, anemia, peripheral neuropathy, leukopenia, dyspepsia, urinary tract infection, pain in extremity.
7	Mechanism	Mechanism of Action	Fosaprepitant is a prodrug of aprepitant and accordingly, its antiemetic effects are attributable to aprepitant. Aprepitant is a selective high-affinity antagonist of human substance P/neurokinin 1(NK1) receptors. Aprepitant has little or no affinity for serotonin (5-HT3), dopamine, and corticosteroid receptors, the targets of existing therapies for chemotherapy-induced nausea and vomiting (CINV). Aprepitant has been shown in animal models to inhibit

			emesis induced by cytotoxic chemotherapeutic agents, such as cisplatin, via central actions. Animal and human Positron Emission Tomography (PET) studies with aprepitant have shown that it crosses the blood brain barrier and occupies brain NK1 receptors. Animal and human studies have shown that aprepitant augments the antiemetic activity of the 5-HT3 -receptor antagonist ondansetron and the corticosteroid dexamethasone and inhibits both the acute and delayed phases of cisplatin-induced emesis.
8	Warning	Black Box Warning	No black box warning
9	Lactation	Use in Lactation	It is not known if fosaprepitant for injection passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive fosaprepitant for injection.
10	Pregnancy	Use in Pregnancy	It is not known if fosaprepitant for injection can harm your unborn baby. Women who use birth control medicines containing hormones to prevent pregnancy (birth control pills, skin patches, implants, and certain IUDs) should also use a backup method of birth control that does not contain hormones, such as condoms and spermicides, during treatment with fosaprepitant for injection and for 1 month after receiving fosaprepitant for injection.
11	Precautions	Is there any interaction between medication and alcohol?	No
12	Storage	What are the storage conditions?	Fosaprepitant for injection vials must be refrigerated, store at 2°C - 8°C (36°F - 46°F). The reconstituted final drug solution is stable for 24 hours at ambient room temperature [at or below 25°C (77°F)].
13	Dispensing	How to Dispense?	Single-dose glass vial containing 150 mg of fosaprepitant as a white to off white lyophilized cake or powder for reconstitution. Supplied as follows: NDC 72205-054-01 1 vial per carton.
14	Contraindication	What are the contraindications of (medication).	Fosaprepitant is contraindicated in patients: • Who are hypersensitive to any component of the product Hypersensitivity reactions including anaphylactic reactions, flushing, erythema, and dyspnoea 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.
Pharmaceutical Particulars			
15	Pharmaceutical Form	How Supplied	Single-dose glass vial containing 150 mg of fosaprepitant as a white to off white lyophilized cake or powder for reconstitution. Supplied as follows: NDC 72205-054-01 1 vial per carton.
16	Ingredients	Active and Inactive	**Active ingredient:** Fosaprepitant dimeglumine **Inactive ingredients:** Edetate disodium, lactose anhydrous, polysorbate 80, sodium hydroxide and/ or hydrochloric acid (for pH adjustment).
Allergens			
17	Ingredients	Does it contain Gluten?	No
18	Ingredients	Does it contain alcohol?	No

19	Ingredients	Does it contain dyes?	No
20	Ingredients	Does it contain Lactose?	Yes
21	Ingredients	Does it contain Nuts?	No
22	Ingredients	Does it contain Preservatives?	No
23	Ingredients	Does it contain Soy products?	Yes (Rubber stopper is used as a primary packing material, which contains trace of epoxidized soybean oil)
24	Ingredients	Does it contain peanut?	No
25	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
26	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
27	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
28	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714
29	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
30	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You can also visit our website www.novadozpharma.com/contact-us/
31	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.