Evaluation of Fosaprepitant (MK0517) in Single Dose Schedule (0517-017) (EASE)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00619359

First received: January 28, 2008
Last updated: February 6, 2015
Last verified: February 2015
History of Changes

Purpose

The purpose of this study is to examine the safety, tolerability, and efficacy of MK0517 to prevent Chemotherapy-Induced Nausea and Vomiting (CINV) associated with Cisplatin chemotherapy.

Condition	Intervention	Phase
Chemotherapy-Induced Nausea and Vomiting (CINV)	Drug: Comparator: fosaprepitant dimeglumine Drug: Comparator: Aprepitant Drug: Dexamethasone Drug: Ondansetron	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Prevention

Official Title: Phase 3, Randomized, Double-Blind, Active-Controlled, Parallel-Group Study, Conducted Under In-House Blinding Conditions, to Examine the Safety, Tolerability & Efficacy of a Single Dose of Intravenous MK0517 for Prevention of Chemotherapy-Induced Nausea & Vomiting Associated With Cisplatin Chemo

Resource links provided by NLM:

MedlinePlus related topics: Nausea and Vomiting

Drug Information available for: Dexamethasone Dexamethasone sodium phosphate Dexamethasone acetate Ondansetron hydrochloride Ondansetron Aprepitant Fosaprepitant Fosaprepitant dimeglumine

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- A Complete Response (no Vomiting and no Use of Rescue Therapy) Overall (in the 120 Hours Following Initiation of Cisplatin). [Time Frame: Overall (in the 120 hours following initiation of cisplatin chemotherapy).] [Designated as safety issue: No]

  The number of patients who reported No Vomiting and No Use of Rescue Therapy in the 120 hours following initiation of cisplatin chemotherapy.

Secondary Outcome Measures:

- A Complete Response (no Vomiting and no Use of Rescue Therapy) in the Delayed Phase (25 to 120 Hours Following Initiation of Cisplatin). [Time Frame: Delayed phase (25 to 120 hours following initiation of cisplatin).] [Designated as safety issue: No]

  The number of patients who reported No Vomiting and No Use of Rescue Therapy in the 25 to 120 hours following initiation of cisplatin chemotherapy.

- No Vomiting Overall (in the 120 Hours Following Initiation of Cisplatin) [Time Frame: Overall (the 120 hours following initiation of cisplatin chemotherapy)] [Designated as safety issue: No]

  The number of patients who reported No Vomiting in the 120 hours following initiation of cisplatin chemotherapy.

Enrollment:	2322
Study Start Date:	February 2008
Study Completion Date:	June 2009
Primary Completion Date:	June 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Arm 1: study medication	Drug: Comparator: fosaprepitant dimeglumine single IV dose of 150 mg of fosaprepitant dimeglumine on Day 1. Drug: Dexamethasone Oral dose of 12 mg of dexamethasone on Day 1, 8 mg on Day 2, and 8 mg twice a day on Days 3-4. Drug: Ondansetron single IV dose of 32 mg of ondansetron on Day 1.
Active Comparator: 2 Arm 2: Active comparator	Drug: Comparator: Aprepitant Aprepitant 3-day dosing oral regimen (125 mg on Day 1 followed by 80 mg on Days 2 and 3). Drug: Dexamethasone Oral dose of 12 mg of dexamethasone on Day 1, and 8 mg on Days 2-4. Drug: Ondansetron single IV dose of 32 mg of ondansetron on Day 1.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient is male or female and is at least 18 years of age; scheduled to receive his or her first course of cisplatin chemotherapy at a dose of 70 mg/m2 or higher; predicted life expectancy of 3 months or greater
- Patient is post menopausal or, if premenopausal, must use double-barrier contraception

Exclusion Criteria:

- Patient has symptomatic primary or metastatic CNS malignancy
- Patient has received or will receive Radiation therapy to the abdomen or pelvis in the week prior to Treatment Day 1 though Day 6

- Patient has vomited in the 24 hours prior to treatment Day 1
- Patient has an active infection; Patient uses illicit drugs or has current evidence of alcohol abuse
- Patient is pregnant or breast feeding

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00619359

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Grunberg S, Chua D, Maru A, Dinis J, DeVandry S, Boice JA, Hardwick JS, Beckford E, Taylor A, Carides A, Roila F, Herrstedt J. Single-dose fosaprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with cisplatin therapy: randomized, double-blind study protocol--EASE. J Clin Oncol. 2011 Apr 10;29(11):1495-501. doi: 10.1200/JCO.2010.31.7859. Epub 2011 Mar 7.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00619359 History of Changes
Other Study ID Numbers:	0517-017 MK0517-017 2007_594
Study First Received:	January 28, 2008
Results First Received:	January 19, 2010
Last Updated:	February 6, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Vomiting	Antipruritics
Signs and Symptoms	Antipsychotic Agents
Signs and Symptoms, Digestive	Autonomic Agents
Aprepitant	Central Nervous System Agents
BB 1101	Central Nervous System Depressants
Dexamethasone	Dermatologic Agents
Dexamethasone 21-phosphate	Enzyme Inhibitors
Dexamethasone acetate	Gastrointestinal Agents
Fosaprepitant	Glucocorticoids
Ondansetron	Hormones
Anti-Anxiety Agents	Hormones, Hormone Substitutes, and Hormone Antagonists
Anti-Inflammatory Agents	Molecular Mechanisms of Pharmacological Action
Antiemetics	Neurokinin-1 Receptor Antagonists
Antineoplastic Agents	Neurotransmitter Agents
Antineoplastic Agents, Hormonal	Peripheral Nervous System Agents

ClinicalTrials.gov processed this record on April 07, 2016

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Results First Received: January 19, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Prevention
Condition:	Chemotherapy-Induced Nausea and Vomiting (CINV)
Interventions:	Drug: Comparator: fosaprepitant dimeglumine Drug: Comparator: Aprepitant Drug: Dexamethasone Drug: Ondansetron

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Patients were recruited from 149 medical centers worldwide. The recruitment period was from 12 Feb 08 through 8 Jun 09.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Cisplatin-naïve patients scheduled to receive cisplatin chemotherapy at a dose of 70 mg/m2 or higher for a documented solid malignancy were screened up to 30 days prior to initiation of chemotherapy. Screening included a complete medical history and physical exam. Informed consent was obtained for patients who agreed to participate in the study.

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4.

Participant Flow: Overall Study

	Fosaprepitant	Aprepitant
STARTED	**1147**	**1175**
COMPLETED	**1080**	**1094**
NOT COMPLETED	**67**	**81**
Adverse Event	**32**	**36**
Lost to Follow-up	**12**	**16**
Physician Decision	**0**	**7**
Protocol Violation	**1**	**1**
Withdrawal by Subject	**19**	**20**
Progressive Disease	**3**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4.
Total	Total of all reporting groups

Baseline Measures

	Fosaprepitant	Aprepitant	Total
Number of Participants [units: participants]	**1147**	**1175**	**2322**
Age [units: years] Mean (Full Range)	**55.2 (19 to 86)**	**55.9 (19 to 82)**	**55.6 (19 to 86)**

Gender [units: participants]			
Female	**425**	**427**	**852**
Male	**722**	**748**	**1470**
Race/Ethnicity, Customized [units: participants]			
American Indian or Alaska Native	**32**	**33**	**65**
Asian	**296**	**306**	**602**
Black or African American	**21**	**22**	**43**
Multi-Racial	**149**	**157**	**306**
Native Hawaiian or Pacific Islander	**1**	**2**	**3**
White	**648**	**655**	**1303**
History of Motion Sickness [1] [units: Participants]			
Yes	**0**	**3**	**3**
No	**1143**	**1166**	**2309**
No Data - Assessment Not Completed	**4**	**6**	**10**
History of Vomiting with Pregnancy [2] [units: Participants]			
Yes	**3**	**3**	**6**
No	**420**	**421**	**841**
Female Patients with No Data - No Assessment	**2**	**3**	**5**
Not Applicable - Male Patients	**722**	**748**	**1470**

[1] Includes treated patients only.
[2] Measure is specific to female treated patients only.

Outcome Measures

Hide All Outcome Measures

1. Primary: A Complete Response (no Vomiting and no Use of Rescue Therapy) Overall (in the 120 Hours Following Initiation of Cisplatin). [Time Frame: Overall (in the 120 hours following initiation of cisplatin chemotherapy).]

Measure Type	Primary
Measure Title	A Complete Response (no Vomiting and no Use of Rescue Therapy) Overall (in the 120 Hours Following Initiation of Cisplatin).
Measure Description	The number of patients who reported No Vomiting and No Use of Rescue Therapy in the 120 hours following initiation of cisplatin chemotherapy.
Time Frame	Overall (in the 120 hours following initiation of cisplatin chemotherapy).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
FAS (Full Analysis Set) patient population was used for all efficacy evaluations and included patients who: 1) received at least one dose of study therapy, 2) received cisplatin chemotherapy, and 3) had at least one post-treatment efficacy assessment.

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4.

Measured Values

	Fosaprepitant	**Aprepitant**
Number of Participants Analyzed [units: participants]	**1106**	**1134**
A Complete Response (no Vomiting and no Use of Rescue Therapy) Overall (in the 120 Hours Following Initiation of Cisplatin). [units: Participants]	**795**	**820**

Statistical Analysis 1 for A Complete Response (no Vomiting and no Use of Rescue Therapy) Overall (in the 120 Hours Following Initiation of Cisplatin).

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Risk Difference (RD) [3]	-0.4
Standard Error of the mean	(3.7)
95% Confidence Interval	-4.1 to 3.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the CI for the difference in response rates (Fosaprepitant minus Aprepitant), calculated using the methodology of Miettinen and Nurminen, had a lower limit ≥7 percentage points, fosaprepitant was considered at least as effective as aprepitant for Complete Response in the overall phase. Study had 90% power to detect non-inferiority for this outcome measure.
[3]	Other relevant estimation information:
	No text entered.

2. Secondary: A Complete Response (no Vomiting and no Use of Rescue Therapy) in the Delayed Phase (25 to 120 Hours Following Initiation of Cisplatin). [Time Frame: Delayed phase (25 to 120 hours following initiation of cisplatin).]

Measure Type	Secondary
	A Complete Response (no Vomiting and no Use of Rescue Therapy) in the Delayed Phase (25 to 120 Hours Following

Measure Title	Initiation of Cisplatin).
Measure Description	The number of patients who reported No Vomiting and No Use of Rescue Therapy in the 25 to 120 hours following initiation of cisplatin chemotherapy.
Time Frame	Delayed phase (25 to 120 hours following initiation of cisplatin).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
FAS (Full Analysis Set) patient population was used for all efficacy evaluations and included patients who: 1) received at least one dose of study therapy, 2) received cisplatin chemotherapy, and 3) had at least one post-treatment efficacy assessment. 1 patient (aprepitant group) had no delayed phase data, and was not included in this analysis.

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4.

Measured Values

	Fosaprepitant	**Aprepitant**
Number of Participants Analyzed [units: participants]	**1106**	**1133**
A Complete Response (no Vomiting and no Use of Rescue Therapy) in the Delayed Phase (25 to 120 Hours Following Initiation of Cisplatin). [units: Participants]	**822**	**841**

Statistical Analysis 1 for A Complete Response (no Vomiting and no Use of Rescue Therapy) in the Delayed Phase (25 to 120 Hours Following Initiation of Cisplatin).

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Risk Difference (RD) [3]	0.1
Standard Error of the mean	(3.6)
95% Confidence Interval	-3.5 to 3.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the CI for the difference in response rates, calculated using the methodology of Miettinen and Nurminen, had a lower limit ≥7.3 percentage points, fosaprepitant was considered at least as effective as aprepitant for Complete Response in the delayed phase.
[3]	Other relevant estimation information:

	No text entered.

3. Secondary: No Vomiting Overall (in the 120 Hours Following Initiation of Cisplatin) [Time Frame: Overall (the 120 hours following initiation of cisplatin chemotherapy)]

Measure Type	Secondary
Measure Title	No Vomiting Overall (in the 120 Hours Following Initiation of Cisplatin)
Measure Description	The number of patients who reported No Vomiting in the 120 hours following initiation of cisplatin chemotherapy.
Time Frame	Overall (the 120 hours following initiation of cisplatin chemotherapy)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
FAS (Full Analysis Set) patient population was used for all efficacy evaluations and included patients who: 1) received at least one dose of study therapy, 2) received cisplatin chemotherapy, and 3) had at least one post-treatment efficacy assessment. 2 patients (aprepitant group) had no vomiting data, and were excluded from this analysis.

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4.

Measured Values

	Fosaprepitant	**Aprepitant**
Number of Participants Analyzed [units: participants]	**1106**	**1132**
No Vomiting Overall (in the 120 Hours Following Initiation of Cisplatin) [units: Participants]	**806**	**844**

Statistical Analysis 1 for No Vomiting Overall (in the 120 Hours Following Initiation of Cisplatin)

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Risk Difference (RD) [3]	-1.7
Standard Error of the mean	(3.6)
95% Confidence Interval	-5.3 to 2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	If the CI for the difference in response rates, calculated using the methodology of Miettinen and Nurminen, had a lower limit ≥8.2 percentage points, fosaprepitant was considered at least as effective as aprepitant for No Vomiting in the overall phase.
[3]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	AEs were collected starting from the Pre-Study Visit (Day -30 to Day -1) up to 14 days after the patient's last dose of study drug.
Additional Description	Severe infusion site pain, severe infusion site erythema and/or severe infusion site induration, as well as any episode of infusion site thrombophlebitis were designated Events of Clinical Interest (ECI) and evaluated using a predefined severity assessment scale.

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4. 4 patients from the fosaprepitant regimen were randomized to the study, but discontinued before receiving study drug. These patients were excluded from the Adverse Event tables.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4. 6 patients from the aprepitant regimen were randomized to the study, but discontinued before receiving study drug. These patients were excluded from the Adverse Event tables.

Serious Adverse Events

	Fosaprepitant	Aprepitant
Total, serious adverse events		
# participants affected / at risk	**148/1143 (12.95%)**	**157/1169 (13.43%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**3/1143 (0.26%)**	**3/1169 (0.26%)**
Febrile neutropenia * 1		
# participants affected / at risk	**18/1143 (1.57%)**	**27/1169 (2.31%)**
Leukopenia * 1		
# participants affected / at risk	**4/1143 (0.35%)**	**2/1169 (0.17%)**
Neutropenia * 1		
# participants affected / at risk	**17/1143 (1.49%)**	**13/1169 (1.11%)**
Pancytopenia * 1		

# participants affected / at risk	3/1143 (0.26%)	0/1169 (0.00%)
Thrombocytopenia * 1		
# participants affected / at risk	2/1143 (0.17%)	2/1169 (0.17%)
Cardiac disorders		
Atrial fibrillation * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Cardiac arrest * 1		
# participants affected / at risk	1/1143 (0.09%)	2/1169 (0.17%)
Cardio-respiratory arrest * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Cardiopulmonary failure * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Myocardial infarction * 1		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Palpitations * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Supraventricular tachycardia * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Ear and labyrinth disorders		
Vertigo * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Eye disorders		
Conjunctival haemorrhage * 1		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Diplopia * 1		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Gastrointestinal disorders		
Abdominal pain * 1		
# participants affected / at risk	1/1143 (0.09%)	4/1169 (0.34%)
Abdominal pain upper * 1		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Constipation * 1		
# participants affected / at risk	2/1143 (0.17%)	1/1169 (0.09%)
Diarrhoea * 1		
# participants affected / at risk	3/1143 (0.26%)	8/1169 (0.68%)
Duodenal ulcer perforation * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Dysphagia * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Enteritis * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)

Faecaloma [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Gastric perforation [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Gastric ulcer haemorrhage [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Gastric ulcer perforation [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Gastritis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Gastritis erosive [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Gastrointestinal haemorrhage [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Gastrointestinal necrosis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Haematemesis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**1/1169 (0.09%)**
Haematochezia [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Haemorrhoidal haemorrhage [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Intestinal obstruction [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**2/1169 (0.17%)**
Melaena [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Nausea [*1]		
# participants affected / at risk	**4/1143 (0.35%)**	**3/1169 (0.26%)**
Oesophageal varices haemorrhage [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Regurgitation [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Stomatitis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Upper gastrointestinal haemorrhage [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**1/1169 (0.09%)**
Vomiting [*1]		
# participants affected / at risk	**13/1143 (1.14%)**	**7/1169 (0.60%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**4/1143 (0.35%)**	**8/1169 (0.68%)**
[*1]		

Chest pain		
# participants affected / at risk	**1/1143 (0.09%)**	**1/1169 (0.09%)**
Death [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**5/1169 (0.43%)**
Fatigue [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Mucosal inflammation [*1]		
# participants affected / at risk	**3/1143 (0.26%)**	**2/1169 (0.17%)**
Non-cardiac chest pain [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Pain [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**2/1169 (0.17%)**
Pyrexia [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**2/1169 (0.17%)**
Suprapubic pain [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Hepatobiliary disorders		
Acute hepatic failure [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Hepatic failure [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Hyperbilirubinaemia [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Infections and infestations		
Abdominal infection [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Appendicitis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Bacteraemia [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Cellulitis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Cystitis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**2/1169 (0.17%)**
Diarrhoea infectious [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Gastroenteritis [*1]		
# participants affected / at risk	**3/1143 (0.26%)**	**5/1169 (0.43%)**
Gastroenteritis shigella [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Herpes virus infection [*1]		

# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Herpes zoster [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Incision site abscess [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Lower respiratory tract infection [*1]		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Oesophageal candidiasis [*1]		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Perineal abscess [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Pneumonia [*1]		
# participants affected / at risk	3/1143 (0.26%)	9/1169 (0.77%)
Postoperative wound infection [*1]		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Pyelonephritis [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Respiratory tract infection [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Sepsis [*1]		
# participants affected / at risk	5/1143 (0.44%)	1/1169 (0.09%)
Septic shock [*1]		
# participants affected / at risk	4/1143 (0.35%)	1/1169 (0.09%)
Upper respiratory tract infection [*1]		
# participants affected / at risk	1/1143 (0.09%)	1/1169 (0.09%)
Urinary tract infection [*1]		
# participants affected / at risk	2/1143 (0.17%)	0/1169 (0.00%)
Wound infection [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Injury, poisoning and procedural complications		
Tracheal obstruction [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Wound dehiscence [*1]		
# participants affected / at risk	0/1143 (0.00%)	1/1169 (0.09%)
Investigations		
Alanine aminotransferase increased [*1]		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Aspartate aminotransferase increased [*1]		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Blood creatinine increased [*1]		
# participants affected / at risk	2/1143 (0.17%)	1/1169 (0.09%)

Blood potassium decreased [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**2/1169 (0.17%)**
Haemoglobin decreased [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Liver function test abnormal [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Neutrophil count decreased [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**1/1169 (0.09%)**
Metabolism and nutrition disorders		
Anorexia [*1]		
# participants affected / at risk	**3/1143 (0.26%)**	**5/1169 (0.43%)**
Dehydration [*1]		
# participants affected / at risk	**12/1143 (1.05%)**	**9/1169 (0.77%)**
Diabetes mellitus [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Hyperglycaemia [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Hypokalaemia [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Hyponatraemia [*1]		
# participants affected / at risk	**5/1143 (0.44%)**	**2/1169 (0.17%)**
Malnutrition [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Musculoskeletal and connective tissue disorders		
Flank pain [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Lung neoplasm malignant [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Malignant neoplasm progression [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**2/1169 (0.17%)**
Metastases to central nervous system [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Paraneoplastic syndrome [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Tumour haemorrhage [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Nervous system disorders		
Cerebral ischaemia [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**

Cerebrovascular accident [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**2/1169 (0.17%)**
Cognitive disorder [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Convulsion [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**1/1169 (0.09%)**
Dizziness [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Haemorrhage intracranial [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Ischaemic stroke [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Spinal cord compression [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Psychiatric disorders		
Disorientation [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Psychotic disorder [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Renal and urinary disorders		
Hydronephrosis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Renal failure [*1]		
# participants affected / at risk	**3/1143 (0.26%)**	**2/1169 (0.17%)**
Renal failure acute [*1]		
# participants affected / at risk	**3/1143 (0.26%)**	**1/1169 (0.09%)**
Renal failure chronic [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Renal impairment [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Urinary retention [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**2/1169 (0.17%)**
Respiratory, thoracic and mediastinal disorders		
Aspiration [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Choking [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Dyspnoea [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**5/1169 (0.43%)**
Epistaxis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**

Haemoptysis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Hiccups [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**1/1169 (0.09%)**
Hydropneumothorax [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Pleural effusion [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**2/1169 (0.17%)**
Pneumonia aspiration [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Pneumonitis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Pulmonary embolism [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**1/1169 (0.09%)**
Pulmonary thrombosis [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Respiratory arrest [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Respiratory distress [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Respiratory failure [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**3/1169 (0.26%)**
Skin and subcutaneous tissue disorders		
Erythema [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Vascular disorders		
Arterial occlusive disease [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Arterial thrombosis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Arteriosclerosis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Deep vein thrombosis [*1]		
# participants affected / at risk	**2/1143 (0.17%)**	**0/1169 (0.00%)**
Flushing [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Hypertension [*1]		
# participants affected / at risk	**0/1143 (0.00%)**	**1/1169 (0.09%)**
Hypertensive crisis [*1]		
# participants affected / at risk	**1/1143 (0.09%)**	**0/1169 (0.00%)**
Hypotension [*1]		

# participants affected / at risk	1/1143 (0.09%)	2/1169 (0.17%)
Orthostatic hypotension * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Peripheral arterial occlusive disease * 1		
# participants affected / at risk	0/1143 (0.00%)	3/1169 (0.26%)
Peripheral embolism * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)
Thrombosis * 1		
# participants affected / at risk	1/1143 (0.09%)	0/1169 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	AEs were collected starting from the Pre-Study Visit (Day -30 to Day -1) up to 14 days after the patient's last dose of study drug.
Additional Description	Severe infusion site pain, severe infusion site erythema and/or severe infusion site induration, as well as any episode of infusion site thrombophlebitis were designated Events of Clinical Interest (ECI) and evaluated using a predefined severity assessment scale.

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
Fosaprepitant	Fosaprepitant dimeglumine 150 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg by mouth (PO) on Day 1, dexamethasone 8 mg PO on Day 2, and dexamethasone 16 mg PO on Days 3 and 4. 4 patients from the fosaprepitant regimen were randomized to the study, but discontinued before receiving study drug. These patients were excluded from the Adverse Event tables.
Aprepitant	Aprepitant 125 mg by mouth (PO), ondansetron 32 mg IV, and dexamethasone 12 mg PO on Day 1, aprepitant 80 mg PO and dexamethasone 8 mg PO on Days 2 and 3, dexamethasone 8 mg PO on Day 4. 6 patients from the aprepitant regimen were randomized to the study, but discontinued before receiving study drug. These patients were excluded from the Adverse Event tables.

Other Adverse Events

	Fosaprepitant	Aprepitant
Total, other (not including serious) adverse events		
# participants affected / at risk	**636/1143 (55.64%)**	**679/1169 (58.08%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**17/1143 (1.49%)**	**7/1169 (0.60%)**

Leukopenia [*1]		
# participants affected / at risk	**14/1143 (1.22%)**	**16/1169 (1.37%)**
Neutropenia [*1]		
# participants affected / at risk	**28/1143 (2.45%)**	**25/1169 (2.14%)**
Thrombocytopenia [*1]		
# participants affected / at risk	**17/1143 (1.49%)**	**14/1169 (1.20%)**
Ear and labyrinth disorders		
Tinnitus [*1]		
# participants affected / at risk	**19/1143 (1.66%)**	**10/1169 (0.86%)**
Gastrointestinal disorders		
Abdominal pain [*1]		
# participants affected / at risk	**34/1143 (2.97%)**	**35/1169 (2.99%)**
Abdominal pain upper [*1]		
# participants affected / at risk	**46/1143 (4.02%)**	**29/1169 (2.48%)**
Constipation [*1]		
# participants affected / at risk	**119/1143 (10.41%)**	**111/1169 (9.50%)**
Diarrhoea [*1]		
# participants affected / at risk	**86/1143 (7.52%)**	**95/1169 (8.13%)**
Dyspepsia [*1]		
# participants affected / at risk	**50/1143 (4.37%)**	**38/1169 (3.25%)**
Gastritis [*1]		
# participants affected / at risk	**12/1143 (1.05%)**	**9/1169 (0.77%)**
Nausea [*1]		
# participants affected / at risk	**64/1143 (5.60%)**	**78/1169 (6.67%)**
Stomatitis [*1]		
# participants affected / at risk	**20/1143 (1.75%)**	**18/1169 (1.54%)**
Vomiting [*1]		
# participants affected / at risk	**62/1143 (5.42%)**	**58/1169 (4.96%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**94/1143 (8.22%)**	**129/1169 (11.04%)**
Chest pain [*1]		
# participants affected / at risk	**15/1143 (1.31%)**	**18/1169 (1.54%)**
Fatigue [*1]		
# participants affected / at risk	**53/1143 (4.64%)**	**56/1169 (4.79%)**
Infusion site pain [*1]		
# participants affected / at risk	**16/1143 (1.40%)**	**1/1169 (0.09%)**
Mucosal inflammation [*1]		
# participants affected / at risk	**22/1143 (1.92%)**	**32/1169 (2.74%)**
Pain [*1]		
# participants affected / at risk	**11/1143 (0.96%)**	**10/1169 (0.86%)**

Pyrexia [*1]		
# participants affected / at risk	**22/1143 (1.92%)**	**23/1169 (1.97%)**
Injury, poisoning and procedural complications		
Accidental overdose [*1]		
# participants affected / at risk	**11/1143 (0.96%)**	**13/1169 (1.11%)**
Investigations		
Alanine aminotransferase increased [*1]		
# participants affected / at risk	**15/1143 (1.31%)**	**17/1169 (1.45%)**
Blood creatinine increased [*1]		
# participants affected / at risk	**14/1143 (1.22%)**	**12/1169 (1.03%)**
Metabolism and nutrition disorders		
Anorexia [*1]		
# participants affected / at risk	**74/1143 (6.47%)**	**101/1169 (8.64%)**
Dehydration [*1]		
# participants affected / at risk	**20/1143 (1.75%)**	**32/1169 (2.74%)**
Hypokalaemia [*1]		
# participants affected / at risk	**13/1143 (1.14%)**	**10/1169 (0.86%)**
Hyponatraemia [*1]		
# participants affected / at risk	**10/1143 (0.87%)**	**13/1169 (1.11%)**
Musculoskeletal and connective tissue disorders		
Myalgia [*1]		
# participants affected / at risk	**16/1143 (1.40%)**	**17/1169 (1.45%)**
Pain in extremity [*1]		
# participants affected / at risk	**18/1143 (1.57%)**	**16/1169 (1.37%)**
Nervous system disorders		
Dizziness [*1]		
# participants affected / at risk	**38/1143 (3.32%)**	**34/1169 (2.91%)**
Dysgeusia [*1]		
# participants affected / at risk	**14/1143 (1.22%)**	**14/1169 (1.20%)**
Headache [*1]		
# participants affected / at risk	**46/1143 (4.02%)**	**48/1169 (4.11%)**
Psychiatric disorders		
Insomnia [*1]		
# participants affected / at risk	**14/1143 (1.22%)**	**19/1169 (1.63%)**
Respiratory, thoracic and mediastinal disorders		
Cough [*1]		
# participants affected / at risk	**26/1143 (2.27%)**	**22/1169 (1.88%)**
Dyspnoea [*1]		
# participants affected / at risk	**16/1143 (1.40%)**	**15/1169 (1.28%)**
Hiccups [*1]		
# participants affected / at risk	**63/1143 (5.51%)**	**74/1169 (6.33%)**

Skin and subcutaneous tissue disorders		
Alopecia [*1]		
# participants affected / at risk	**12/1143 (1.05%)**	**16/1169 (1.37%)**
Erythema [*1]		
# participants affected / at risk	**13/1143 (1.14%)**	**4/1169 (0.34%)**
Vascular disorders		
Hypertension [*1]		
# participants affected / at risk	**17/1143 (1.49%)**	**6/1169 (0.51%)**
Hypotension [*1]		
# participants affected / at risk	**11/1143 (0.96%)**	**12/1169 (1.03%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 12.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

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