Aprepitant for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV)(0869-130) (COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00337727

First received: June 14, 2006
Last updated: June 8, 2015
Last verified: June 2015
History of Changes

Purpose

The study will test aprepitant for the prevention of CINV in patients receiving their initial cycle of Moderately Emetogenic Chemotherapy (MEC). Patients receiving more then one cycle of chemotherapy may opt to participate in an optional second cycle during which the patient will receive the same antiemetic regimen as cycle 1, except that an IV formulation of aprepitant will be given in place of the oral formulation on study day one. Study drug administration on subsequent days will be given orally as in cycle 1.

Condition	Intervention	Phase
Chemotherapy-Induced Nausea and Vomiting	Drug: aprepitant Drug: Comparator: ondansetron Drug: Comparator: dexamethasone Drug: Comparator: fosaprepitant dimeglumine Drug: Comparator; Placebo (unspecified)	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: A Randomized, Double-Blind, Parallel-Group Study Conducted Under In-House Blinding Conditions to Determine the Efficacy and Tolerability of Aprepitant for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) Associated With Moderately Emetogenic Chemotherapy (MEC)

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:

- Number of Patients Who Reported No Vomiting [Time Frame: Overall phase (0-120 hours post initiation of MEC) in Cycle 1.] [Designated as safety issue: No]

  The number of patients who reported No Vomiting in the overall phase in Cycle 1

Secondary Outcome Measures:

- Number of Patients Who Reported Complete Response [Time Frame: Overall phase (0-120 hours post initiation of MEC) in Cycle 1] [Designated as safety issue: No]

  The number of patients who reported Complete Response (no vomiting and no use of rescue medication) in the overall phase in Cycle 1.

Enrollment: 848
Study Start Date: January 2007
Study Completion Date: November 2008
Primary Completion Date: October 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1 Arm 1: Day 1: aprepitant 125 mg capsule; ondansetron 8 mg capsule prior to chemotherapy and 1 8mg capsule 12 hrs after first dose; dexamethasone 12 mg tablets + 2 dexamethasone Pbo tablets. Day 2: Aprepitant 80 mg capsule; Ondansetron 8 mg capsule every 12 hours Day 3: Aprepitant 80 mg capsule Ondansetron 8 mg capsule every 12 hours.	Drug: aprepitant aprepitant 125 mg capsule; aprepitant 80 mg capsule Three day treatment period. Other Name: MK0869 Drug: Comparator: ondansetron Ondansetron 8 mg capsule Three day treatment period. Other Name: Zofran® Drug: Comparator: dexamethasone dexamethasone 12 mg tablets; 20 mg tablets Three day treatment period. Other Name: DEXAMETHASONE TABLETS USP Drug: Comparator; Placebo (unspecified) dexamethasone 12mg Pbo tablets.
2 Arm 2: Day 1: Aprepitant 125 mg Pbo capsule; Ondansetron 8 mg capsule prior to chemotherapy and 8 mg capsule 12 hours after first dose; Dexamethasone 20 mg tablets. Day 2: Aprepitant 80 mg Pbo capsule; Ondansetron 8 mg capsule every 12 hours; Day 3: Aprepitant 80 mg Pbo capsule; Ondansetron 8 mg capsule every 12 hours. 3 Day treatment period Optional cycle 2 is being offered to patients. Optional cycle 2 will substitute aprepitant with fosaprepitant	Drug: Comparator: ondansetron Ondansetron 8 mg capsule Three day treatment period.

dimeglumine 115 mg or Pbo on day 1. All other dosing regimen will remain the same as cycle 1.	Other Name: Zofran® Drug: Comparator: dexamethasone dexamethasone 12 mg tablets; 20 mg tablets Three day treatment period. Other Name: DEXAMETHASONE TABLETS USP Drug: Comparator: fosaprepitant dimeglumine fosaprepitant dimeglumine 115 mg Other Name: EMEND® Drug: Comparator; Placebo (unspecified) Aprepitant 80 mg & 125 mg Pbo capsules.

Eligibility

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

Criteria

Inclusion Criteria:

- Patients will be naive to emetogenic chemotherapy with histologically or cytologically confirmed malignant disease scheduled to receive a single dose of moderately emetogenic chemotherapy on study day 1
- Karnofsky score of 60 or greater

Exclusion Criteria:

- Patient is scheduled to receive any dose of cisplatin
- Patient will receive abdominal or pelvic radiation a week prior and up to 6 days after initiation of chemotherapy
- Any allergies to study drug or antiemetics
- Taking CYP3A4 substrates/prohibited medication
- Significant medical or mental conditions
- Abnormal laboratory values (platelets, absolute neutrophils, AST, ALT, bilirubin or creatinine).

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: NCT00337727

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

(MedWatch - FDA maintained medical product safety Information) EXIT

(Merck: Patient & Caregiver U.S. Product Web Site) EXIT

Publications:

Rapoport BL, Jordan K, Boice JA, Taylor A, Brown C, Hardwick JS, Carides A, Webb T, Schmoll HJ. Aprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with a broad range of moderately emetogenic chemotherapies and tumor types: a randomized, double-blind study. Support Care Cancer. 2010 Apr;18(4):423-31. doi: 10.1007/s00520-009-0680-9. Epub 2009 Jul 1.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Rapoport BL. Efficacy of a triple antiemetic regimen with aprepitant for the prevention of chemotherapy-induced nausea and vomiting: effects of gender, age, and region. Curr Med Res Opin. 2014 Sep;30(9):1875-81. doi: 10.1185/03007995.2014.925866. Epub 2014 Jun 12.

Aapro MS, Schmoll HJ, Jahn F, Carides AD, Webb RT. Review of the efficacy of aprepitant for the prevention of chemotherapy-induced nausea and vomiting in a range of tumor types. Cancer Treat Rev. 2013 Feb;39(1):113-7. doi: 10.1016/j.ctrv.2012.09.002. Epub 2012 Oct 11. Review.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00337727 History of Changes
Other Study ID Numbers:	0869-130, 2006_016
Study First Received:	June 14, 2006
Results First Received:	September 30, 2009
Last Updated:	June 8, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Nausea	Antineoplastic Agents, Hormonal
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

ClinicalTrials.gov processed this record on July 20, 2015

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Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: September 30, 2009

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
Interventions:	Drug: aprepitant Drug: Comparator: ondansetron Drug: Comparator: dexamethasone Drug: Comparator: fosaprepitant dimeglumine Drug: Comparator; Placebo (unspecified)

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

This study was conducted at 58 investigative sites worldwide. The first patient entered the study on 16-Jan-2007 and the last patient's last visit was on 28-Oct-2008.

Pre-Assignment Details

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

Cancer patients naïve to both moderately and highly emetogenic chemotherapy (MEC and HEC, respectively) scheduled to receive an initial course of MEC for confirmed malignant disease. The study focused on patients receiving an initial cycle of MEC (Cycle 1).

Reporting Groups

	Description
Aprepitant Regimen	Aprepitant 125mg by mouth (PO) plus ondansetron 8mg PO twice daily and dexamethasone 12mg PO on Day 1 and aprepitant 80mg PO once daily on Days 2 and 3.
Standard Regimen	Ondansetron 8mg PO twice daily plus dexamethasone 20mg PO on Day 1 and ondansetron 8mg PO twice daily on Days 2 and 3.

Participant Flow: Overall Study

	Aprepitant Regimen	Standard Regimen
STARTED	**430**	**418**
COMPLETED	**412**	**406**
NOT COMPLETED	**18**	**12**
Adverse Event	**5**	**3**
Lost to Follow-up	**5**	**4**
Physician Decision	**1**	**0**
Protocol Violation	**4**	**0**
Withdrawal by Subject	**3**	**5**

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
Aprepitant Regimen	Aprepitant 125mg by mouth (PO) plus ondansetron 8mg PO twice daily and dexamethasone 12mg PO on Day 1 and aprepitant 80mg PO once daily on Days 2 and 3.
Standard Regimen	Ondansetron 8mg PO twice daily plus dexamethasone 20mg PO on Day 1 and ondansetron 8mg PO twice daily on Days 2 and 3.
Total	Total of all reporting groups

Baseline Measures

	Aprepitant Regimen	Standard Regimen	Total
Number of Participants [units: participants]	**430**	**418**	**848**
Age [units: years] Mean (Standard Deviation)	**57.1 (11.8)**	**55.9 (12.6)**	**56.5 (12.2)**
Gender [units: participants]			

Female	**327**	**325**	**652**
Male	**103**	**93**	**196**
Race/Ethnicity, Customized [units: participants]			
Caucasian	**287**	**296**	**583**
Asian	**49**	**35**	**84**
Black	**26**	**20**	**46**
Multi-racial	**50**	**53**	**103**
Other	**18**	**14**	**32**
History of Motion Sickness [units: Participants]			
Yes	**24**	**41**	**65**
No	**405**	**376**	**781**
No Data – Assessment Not Completed	**1**	**1**	**2**
History of Vomiting with Pregnancy [1] [units: Participants]			
Yes	**61**	**75**	**136**
No	**266**	**250**	**516**
Not Applicable- Male Patients	**103**	**93**	**196**

[1] Measure is specific to the female study population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Patients Who Reported No Vomiting [Time Frame: Overall phase (0-120 hours post initiation of MEC) in Cycle 1.]

Measure Type	Primary
Measure Title	Number of Patients Who Reported No Vomiting
Measure Description	The number of patients who reported No Vomiting in the overall phase in Cycle 1
Time Frame	Overall phase (0-120 hours post initiation of MEC) in Cycle 1.
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 Moderately Emetogenic Chemotherapy (MEC), (2) took a dose of study drug, and (3) completed at least one post treatment efficacy assessment.

Reporting Groups

	Description
Aprepitant Regimen	Aprepitant 125mg by mouth (PO) plus ondansetron 8mg PO twice daily and dexamethasone 12mg PO on Day 1 and

	aprepitant 80mg PO once daily on Days 2 and 3.
Standard Regimen	Ondansetron 8mg PO twice daily plus dexamethasone 20mg PO on Day 1 and ondansetron 8mg PO twice daily on Days 2 and 3.

Measured Values

	Aprepitant Regimen	Standard Regimen
Number of Participants Analyzed [units: participants]	**425**	**406**
Number of Patients Who Reported No Vomiting [units: Participants]	**324**	**252**

Statistical Analysis 1 for Number of Patients Who Reported No Vomiting

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<0.01

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Superiority based on 2-sided level of significance of 0.05, based on a logistic regression model that included terms for treatment group, region and gender.

2. Secondary: Number of Patients Who Reported Complete Response [Time Frame: Overall phase (0-120 hours post initiation of MEC) in Cycle 1]

Measure Type	Secondary
Measure Title	Number of Patients Who Reported Complete Response
Measure Description	The number of patients who reported Complete Response (no vomiting and no use of rescue medication) in the overall phase in Cycle 1.
Time Frame	Overall phase (0-120 hours post initiation of MEC) in Cycle 1
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 MEC, (2) took a dose of study drug, and (3) completed at least one post treatment efficacy assessment.

Reporting Groups

	Description

Aprepitant Regimen	Aprepitant 125mg by mouth (PO) plus ondansetron 8mg PO twice daily and dexamethasone 12mg PO on Day 1 and aprepitant 80mg PO once daily on Days 2 and 3.
Standard Regimen	Ondansetron 8mg PO twice daily plus dexamethasone 20mg PO on Day 1 and ondansetron 8mg PO twice daily on Days 2 and 3.

Measured Values

	Aprepitant Regimen	Standard Regimen
Number of Participants Analyzed [units: participants]	**425**	**407**
Number of Patients Who Reported Complete Response [units: Participants]	**292**	**229**

Statistical Analysis 1 for Number of Patients Who Reported Complete Response

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<0.01

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Superiority based on 2-sided level of significance of 0.05, based on a logistic regression model that included terms for treatment group, region and gender.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Aprepitant Regimen	Aprepitant 125mg by mouth (PO) plus ondansetron 8mg PO twice daily and dexamethasone 12mg PO on Day 1 and aprepitant 80mg PO once daily on Days 2 and 3.
Standard Regimen	Ondansetron 8mg PO twice daily plus dexamethasone 20mg PO on Day 1 and ondansetron 8mg PO twice daily on Days 2 and 3.

Serious Adverse Events

	Aprepitant Regimen	Standard Regimen

Total, serious adverse events		
# participants affected / at risk	**12/430 (2.79%)**	**20/418 (4.78%)**
Blood and lymphatic system disorders		
Febrile Neutropenia [*1]		
# participants affected / at risk	**4/430 (0.93%)**	**3/418 (0.72%)**
Neutropenia [*1]		
# participants affected / at risk	**1/430 (0.23%)**	**1/418 (0.24%)**
Cardiac disorders		
Myocardial Infarction [*1]		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Gastrointestinal disorders		
Abdominal Pain [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Constipation [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Ileitis [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
General disorders		
General physical health deterioration [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Mucosal Inflammation [*1]		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Pyrexia [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Infections and infestations		
Abdominal Infection [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Abscess Limb [*1]		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Cellulitis [*1]		
# participants affected / at risk	**2/430 (0.47%)**	**1/418 (0.24%)**
Herpes Zoster [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Lobar pneumonia [*1]		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Lung Infection [*1]		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Pyelonephritis [*1]		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Injury, poisoning and procedural complications		
[*1]		

Compression Fracture		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Metabolism and nutrition disorders		
Dehydration * 1		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Musculoskeletal and connective tissue disorders		
Bone Pain * 1		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon Cancer * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Nervous system disorders		
Syncope * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Reproductive system and breast disorders		
Vaginal Haemorrhage * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnoea * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Pleural Effusion * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Pneumothorax * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Respiratory Failure * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Vascular disorders		
Arterial Occlusive Disease * 1		
# participants affected / at risk	**0/430 (0.00%)**	**1/418 (0.24%)**
Peripheral Ischemia * 1		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**
Superior Vena Cava Occlusion * 1 [3]		
# participants affected / at risk	**1/430 (0.23%)**	**0/418 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.1
[3] Superior Vena Cava Occlusion

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
Aprepitant Regimen	Aprepitant 125mg by mouth (PO) plus ondansetron 8mg PO twice daily and dexamethasone 12mg PO on Day 1 and aprepitant 80mg PO once daily on Days 2 and 3.
Standard Regimen	Ondansetron 8mg PO twice daily plus dexamethasone 20mg PO on Day 1 and ondansetron 8mg PO twice daily on Days 2 and 3.

Other Adverse Events

	Aprepitant Regimen	Standard Regimen
Total, other (not including serious) adverse events		
# participants affected / at risk	**265/430 (61.63%)**	**270/418 (64.59%)**
Blood and lymphatic system disorders		
Neutropenia [*1]		
# participants affected / at risk	**10/430 (2.33%)**	**9/418 (2.15%)**
Gastrointestinal disorders		
Abdominal Pain [*1]		
# participants affected / at risk	**17/430 (3.95%)**	**16/418 (3.83%)**
Abdominal Pain Upper [*1]		
# participants affected / at risk	**9/430 (2.09%)**	**8/418 (1.91%)**
Constipation [*1]		
# participants affected / at risk	**37/430 (8.60%)**	**53/418 (12.68%)**
Diarrhoea [*1]		
# participants affected / at risk	**40/430 (9.30%)**	**46/418 (11.00%)**
Dyspepsia [*1]		
# participants affected / at risk	**14/430 (3.26%)**	**13/418 (3.11%)**
Nausea [*1]		
# participants affected / at risk	**18/430 (4.19%)**	**11/418 (2.63%)**
Vomiting [*1]		
# participants affected / at risk	**9/430 (2.09%)**	**6/418 (1.44%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**26/430 (6.05%)**	**23/418 (5.50%)**
Fatigue [*1]		
# participants affected / at risk	**47/430 (10.93%)**	**41/418 (9.81%)**
Mucosal Inflammation [*1]		
# participants affected / at risk	**8/430 (1.86%)**	**9/418 (2.15%)**
Metabolism and nutrition disorders		

Anorexia * 1		
# participants affected / at risk	**35/430 (8.14%)**	**37/418 (8.85%)**
Musculoskeletal and connective tissue disorders		
Back Pain * 1		
# participants affected / at risk	**5/430 (1.16%)**	**11/418 (2.63%)**
Myalgia * 1		
# participants affected / at risk	**5/430 (1.16%)**	**9/418 (2.15%)**
Pain in extremity * 1		
# participants affected / at risk	**9/430 (2.09%)**	**5/418 (1.20%)**
Nervous system disorders		
Dizziness * 1		
# participants affected / at risk	**9/430 (2.09%)**	**11/418 (2.63%)**
Dysgeusia * 1		
# participants affected / at risk	**3/430 (0.70%)**	**10/418 (2.39%)**
Headache * 1		
# participants affected / at risk	**42/430 (9.77%)**	**49/418 (11.72%)**
Neuropathy Peripheral * 1		
# participants affected / at risk	**9/430 (2.09%)**	**8/418 (1.91%)**
Paraesthesia * 1		
# participants affected / at risk	**6/430 (1.40%)**	**9/418 (2.15%)**
Skin and subcutaneous tissue disorders		
Alopecia * 1		
# participants affected / at risk	**28/430 (6.51%)**	**32/418 (7.66%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.1

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

Publications of Results:

Rapoport BL, Jordan K, Boice JA, Taylor A, Brown C, Hardwick JS, Carides A, Webb T, Schmoll HJ. Aprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with a broad range of moderately emetogenic chemotherapies and tumor types: a randomized, double-blind study. Support Care Cancer. 2010 Apr;18(4):423-31. doi: 10.1007/s00520-009-0680-9. Epub 2009 Jul 1.

Publications automatically indexed to this study:

Rapoport BL. Efficacy of a triple antiemetic regimen with aprepitant for the prevention of chemotherapy-induced nausea and vomiting: effects of gender, age, and region. Curr Med Res Opin. 2014 Sep;30(9):1875-81. doi: 10.1185/03007995.2014.925866. Epub 2014 Jun 12.

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