ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 02/10/2012

ClinicalTrials.gov ID: NCT00090753

Study Identification

Unique Protocol ID:	BH18387
Brief Title:	A Study of Intravenous or Subcutaneous Methoxy Polyethylene Glycol-Epoetin Beta (RO0503821, Mircera) in Chronic Kidney Disease Patients With Renal Anemia
Official Title:	An Open-label, Multi-center Study to Document the Efficacy, Safety, and Tolerability of Long-term Administration of RO0503821 in Patients With Chronic Renal Anemia
Secondary IDs:	

Study Status

Record Verification:	February 2012
Overall Status:	Completed
Study Start:	October 2004
Primary Completion:	December 2009 [Actual]
Study Completion:	December 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: BB-IND 10158 Serial Number: S-117 Has Expanded Access? No
Review Board:	Approval Status: Approved Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study assessed the long-term efficacy, safety, and tolerability of intravenous (iv) or subcutaneous (sc) methoxy polyethylene glycol-epoetin beta in chronic kidney disease patients with renal anemia. Eligible patients were those who were receiving stable maintenance therapy with methoxy polyethylene glycol-epoetin beta or erythropoiesis stimulating agents (ESAs) in Phase II or III clinical studies. They continued to receive methoxy polyethylene glycol-epoetin beta or comparator ESAs at the same weekly dose and by the same route of administration (sc or iv) as in the qualifying studies.
Detailed Description:	

Conditions

Conditions:	Anemia
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment

Number of Arms:	2
Masking:	Open Label
Allocation:	Non-Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	1228 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Methoxy Polyethylene Glycol-Epoetin Beta Patients received the same weekly dose of methoxy polyethylene glycol-epoetin beta via the same route of administration (iv or sc) as they received in the Phase II or Phase III study that qualified the patient for participation in this study. Methoxy polyethylene glycol-epoetin beta was administered every 2 or every 4 weeks in the initial 104-week treatment period. Patients on a 4-week dosing interval were switched to once-monthly administration in the 24-month extension phase. The dose of methoxy polyethylene glycol-epoetin beta was adjusted to maintain the patient's hemoglobin (Hb) within a target range of 11 to 13 g/dL.	Drug: Methoxy Polyethylene Glycol-Epoetin Beta Methoxy polyethylene glycol-epoetin beta was provided as a sterile single-use injectable solution in 2-mL glass vials containing 1 mL solution or in single-use sterile pre-filled syringes (PFSs) containing 0.3 mL or 0.6 mL injectable solution. The injectable solution was available in vials with the following strengths: 50, 100, 200, 400, and 1000 µg/mL. The injectable solution was available in PFSs with the following strengths: 30, 40, 50, 60, 75, 100, 120, 150, 200, and 250 µg/0.3 mL; and 360 and 400 µg/0.6 mL. Other Names: • RO0503821 • Mircera
Active Comparator: Comparator ESA Patients received the same comparator ESA [epoetin alfa, epoetin beta, or darbepoetin alfa] at the same weekly dose and dosing interval via the same route of administration (iv or sc) as they received in the Phase III study that qualified the patient for participation in this study. The dose of the comparator drug was adjusted to maintain the patient's Hb within a target range of 11 to 13 g/dL. Of the 480 patients in the comparator drug group, 170 received darbepoetin alfa, 134 received epoetin alfa, and 176 received epoetin beta.	Drug: Epoetin alfa Epoetin alfa was provided with commercial packaging in English with country-specific labels (10,000 IU, 20,000 IU). Drug: Epoetin beta Epoetin beta was provided with commercial packaging in English with country-specific labels (50,000 IU, 100,000 IU). Drug: Darbepoetin alfa Darbepoetin alfa was provided with commercial packaging in English with country-specific labels (vials and PFSs in various strengths).

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Written informed consent
- Adult patients (≥ 18 years old) with chronic renal anemia
- Maintenance erythropoietic therapy with methoxy polyethylene glycol-epoetin beta or a protocol-specified reference medication (epoetin alfa formulated with human albumin, epoetin beta or darbepoetin alfa) in one of the following studies: BA16528[NCT00048048], BA16285[NCT00048035], BA16286[NCT00364832], BA16736[NCT00077597], BA16738[NCT00081471], BA16739[NCT00077610], BA16740[NCT00077623], BA17283[NCT00077766] and BA17284[NCT00081484]
- Hemoglobin (Hb) concentration between 10.5 and 13.0 g/dL
- Adequate iron status defined as serum ferritin ≥ 100 ng/mL or Transferrin Saturation (TSAT)≥ 20% or percentage of hypochromic red blood cells (RBCs) < 10%

Exclusion Criteria:

- Poorly controlled hypertension
- History of epileptic seizure
- Pure red cell aplasia
- Chronic congestive heart failure [New York Heart Association (NYHA) IV]
- High likelihood of early withdrawal or interruption of the study
- Active malignant disease (except non-melanoma skin cancer)
- Life expectancy less than 12 months
- Pregnancy or breast-feeding

Contacts/Locations

Study Officials: Clinical Trials
Study Director
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Almería, Spain, 04009

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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Participants were enrolled in one of the following Phase II or Phase III studies: BA16528[NCT00048048], BA16285[NCT00048035], BA16286[NCT00364832], BA16736[NCT00077597], BA16738[NCT00081471], BA16739[NCT00077610], BA16740[NCT00077623], BA17283[NCT00077766] or BA17284[NCT00081484]

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Patients received the same weekly dose of methoxy polyethylene glycol-epoetin beta (Mircera) via the same route of administration (iv or sc) as they received in the Phase II or Phase III study that qualified the patient for participation in this study. Methoxy polyethylene glycol-epoetin beta was administered every 2 or every 4 weeks in the initial 104-week treatment period. Patients on a 4-week dosing interval were switched to once-monthly administration in the 24-month extension phase. The dose of methoxy polyethylene glycol-epoetin beta was adjusted to maintain the patient's hemoglobin (Hb) within a target range of 11 to 13 g/dL.
Comparator ESA	Patients received the same comparator erythropoiesis stimulating agent (ESA) [epoetin alfa, epoetin beta, or darbepoetin alfa] at the same weekly dose and dosing interval via the same route of administration (iv or sc) as they received in the Phase III study that qualified the patient for participation in this study. The dose of the comparator drug was adjusted to maintain the patient's Hb within a target range of 11 to 13 g/dL. Of the 480 patients in the comparator drug group, 170 received darbepoetin alfa, 134 received epoetin alfa, and 176 received epoetin beta.

First Treatment Period

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
Started	748	480
Completed	492	302
Not Completed	256	178
Adverse Event	20	8
Death	88	62
Lack of Efficacy	2	1
Refused Treatment	32	25
Lost to Follow-up	4	4
Renal Transplant	70	50
Mircera Commercialization	1	0
Other Unrelated to Safety and Efficacy	39	28

Extended Treatment Period

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
Started	453 [1]	250 [2]
Completed	94	59
Not Completed	359	191
Adverse Event	11	0
Death	58	30
Lack of Efficacy	1	0
Refused Treatment	18	12
Lost to Follow-up	3	1
Renal Transplant	15	12
Mircera Commercialization	188	93
Other Unrelated to Safety and Efficacy	65	43

[1] 39 patients who completed the first treatment period refused to enter the extended treatment period.
[2] 52 patients who completed the first treatment period refused to enter the extended treatment period.

Baseline Characteristics

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Patients received the same weekly dose of methoxy polyethylene glycol-epoetin beta via the same route of administration (iv or sc) as they received in the Phase II or Phase III study that qualified the patient for participation in this study. Methoxy polyethylene glycol-epoetin beta was administered every 2 or every 4 weeks in the initial 104-week treatment period. Patients on a 4-week dosing interval were switched to once-monthly administration in the 24-month extension phase. The dose of methoxy polyethylene glycol-epoetin beta was adjusted to maintain the patient's hemoglobin (Hb) within a target range of 11 to 13 g/dL.
Comparator ESA	Patients received the same comparator ESA [epoetin alfa, epoetin beta, or darbepoetin alfa] at the same weekly dose and dosing interval via the same route of administration (iv or sc) as they received in the Phase III study that qualified the patient for participation in this study. The dose of the comparator drug was adjusted to maintain the patient's Hb within a target range of 11 to 13 g/dL. Of the 480 patients in the comparator drug group, 170 received darbepoetin alfa, 134 received epoetin alfa, and 176 received epoetin beta.

Baseline Measures

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA	Total
Number of Participants	748	480	1228
Age, Continuous [units: years] Mean (Standard Deviation)	61.2 (14.80)	61.9 (14.42)	61.5 (14.65)
Gender, Male/Female [units: participants]			
Female	327	223	550
Male	421	257	678

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Hemoglobin Concentration to the Last Month of Study Participation
Measure Description	Blood samples were collected at each study visit, that is, every 4 weeks for the first 12 weeks, every 12 weeks until week 105 of the first study period, every 3 months thereafter, and at the end of study or the last visit if the patient discontinued the study prematurely.
Time Frame	Baseline to the end of the study (Up to 49 Months)
Safety Issue?	No

Analysis Population Description

Analysis includes participants from the Intent-to-treat population (all patients who received at least 1 dose of methoxy polyethylene glycol-epoetin beta or a comparator ESA) who had hemoglobin values available for analysis.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Patients received the same weekly dose of methoxy polyethylene glycol-epoetin beta via the same route of administration (iv or sc) as they received in the Phase II or Phase III study that qualified the patient for participation in this study. Methoxy polyethylene glycol-epoetin beta was administered every 2 or every 4 weeks in the initial 104-week treatment period. Patients on a 4-week dosing interval were switched to once-monthly administration in the 24-month extension phase. The dose of methoxy polyethylene glycol-epoetin beta was adjusted to maintain the patient's hemoglobin (Hb) within a target range of 11 to 13 g/dL.
Comparator ESA	Patients received the same comparator ESA [epoetin alfa, epoetin beta, or darbepoetin alfa] at the same weekly dose and dosing interval via the same route of administration (iv or sc) as they received in the Phase III study that qualified the patient for participation in this study. The dose of the comparator drug was adjusted to maintain the patient's Hb within a target range of 11 to 13 g/dL. Of the 480 patients in the comparator drug group, 170 received darbepoetin alfa, 134 received epoetin alfa, and 176 received epoetin beta.

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
Number of Participants Analyzed	735	476
Change From Baseline in Hemoglobin Concentration to the Last Month of Study Participation [units: g/dL] Mean (Standard Deviation)	-0.55 (1.832)	-0.38 (1.614)

2. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Had at Least 1 Adverse Event
Measure Description	See the adverse events section of the results for more information.
Time Frame	From first dose of study drug to date of last contact or 30 days after last drug dose (Up to 49 months)
Safety Issue?	Yes

Analysis Population Description

Intent-to-treat population: All patients who received at least 1 dose of methoxy polyethylene glycol-epoetin beta or a comparator ESA.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Patients received the same weekly dose of methoxy polyethylene glycol-epoetin beta via the same route of administration (iv or sc) as they received in the Phase II or Phase III study that qualified the patient for participation in this study. Methoxy polyethylene glycol-epoetin beta was administered every 2 or every 4 weeks in the initial 104-week treatment period. Patients on a 4-week dosing interval were switched to once-monthly administration in the 24-month extension phase. The dose of methoxy polyethylene glycol-epoetin beta was adjusted to maintain the patient's hemoglobin (Hb) within a target range of 11 to 13 g/dL.
Comparator ESA	Patients received the same comparator ESA [epoetin alfa, epoetin beta, or darbepoetin alfa] at the same weekly dose and dosing interval via the same route of administration (iv or sc) as they received in the Phase III study that qualified the patient for participation in this study. The dose of the comparator drug was adjusted to maintain the patient's Hb within a target range of 11 to 13 g/dL. Of the 480 patients in the comparator drug group, 170 received darbepoetin alfa, 134 received epoetin alfa, and 176 received epoetin beta.

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
Number of Participants Analyzed	748	480
Percentage of Patients Who Had at Least 1 Adverse Event [units: Percentage of participants]	94.3	93.3

Reported Adverse Events

Time Frame	From first dose of study drug to date of last contact or 30 days after last drug dose (Up to 49 months)
Additional Description	Intent-to-treat population: All patients who received at least 1 dose of methoxy polyethylene glycol-epoetin beta or a comparator ESA.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Patients received the same weekly dose of methoxy polyethylene glycol-epoetin beta via the same route of administration (iv or sc) as they received in the Phase II or Phase III study that qualified the patient for participation in this study. Methoxy polyethylene glycol-epoetin beta was administered every 2 or every 4 weeks in the initial 104-week treatment period. Patients on a 4-week dosing interval were switched to once-monthly administration in the 24-month extension phase. The dose of methoxy polyethylene glycol-epoetin beta was adjusted to maintain the patient's hemoglobin (Hb) within a target range of 11 to 13 g/dL.

	Description
Comparator ESA	Patients received the same comparator ESA [epoetin alfa, epoetin beta, or darbepoetin alfa] at the same weekly dose and dosing interval via the same route of administration (iv or sc) as they received in the Phase III study that qualified the patient for participation in this study. The dose of the comparator drug was adjusted to maintain the patient's Hb within a target range of 11 to 13 g/dL. Of the 480 patients in the comparator drug group, 170 received darbepoetin alfa, 134 received epoetin alfa, and 176 received epoetin beta.

Serious Adverse Events

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
Total	499/748 (66.71%)	316/480 (65.83%)
Blood and lymphatic system disorders		
ANAEMIA [A] †	10/748 (1.34%)	6/480 (1.25%)
COAGULOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
DISSEMINATED INTRAVASCULAR COAGULATION [A] †	1/748 (0.13%)	0/480 (0%)
HEPARIN-INDUCED THROMBOCYTOPENIA [A] †	1/748 (0.13%)	0/480 (0%)
HYPOPROTHROMBINAEMIA [A] †	0/748 (0%)	1/480 (0.21%)
LEUKOPENIA [A] †	0/748 (0%)	1/480 (0.21%)
THROMBOCYTOPENIA [A] †	1/748 (0.13%)	0/480 (0%)
Cardiac disorders		
ACUTE CORONARY SYNDROME [A] †	10/748 (1.34%)	3/480 (0.63%)
ACUTE MYOCARDIAL INFARCTION [A] †	26/748 (3.48%)	10/480 (2.08%)
ANGINA PECTORIS [A] †	16/748 (2.14%)	9/480 (1.88%)
ANGINA UNSTABLE [A] †	4/748 (0.53%)	0/480 (0%)
AORTIC VALVE STENOSIS [A] †	0/748 (0%)	1/480 (0.21%)
ARRHYTHMIA [A] †	4/748 (0.53%)	2/480 (0.42%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
ARTERIOSCLEROSIS CORONARY ARTERY [A] †	3/748 (0.4%)	0/480 (0%)
ATRIAL FIBRILLATION [A] †	16/748 (2.14%)	19/480 (3.96%)
ATRIAL FLUTTER [A] †	7/748 (0.94%)	3/480 (0.63%)
ATRIOVENTRICULAR BLOCK [A] †	1/748 (0.13%)	1/480 (0.21%)
ATRIOVENTRICULAR BLOCK COMPLETE [A] †	1/748 (0.13%)	3/480 (0.63%)
ATRIOVENTRICULAR BLOCK FIRST DEGREE [A] †	1/748 (0.13%)	0/480 (0%)
ATRIOVENTRICULAR DISSOCIATION [A] †	1/748 (0.13%)	0/480 (0%)
BRADYCARDIA [A] †	8/748 (1.07%)	1/480 (0.21%)
BUNDLE BRANCH BLOCK RIGHT [A] †	1/748 (0.13%)	0/480 (0%)
CARDIAC ARREST [A] †	16/748 (2.14%)	11/480 (2.29%)
CARDIAC FAILURE [A] †	5/748 (0.67%)	3/480 (0.63%)
CARDIAC FAILURE ACUTE [A] †	0/748 (0%)	1/480 (0.21%)
CARDIAC FAILURE CHRONIC [A] †	1/748 (0.13%)	1/480 (0.21%)
CARDIAC FAILURE CONGESTIVE [A] †	19/748 (2.54%)	21/480 (4.37%)
CARDIO-RESPIRATORY ARREST [A] †	5/748 (0.67%)	6/480 (1.25%)
CARDIOGENIC SHOCK [A] †	4/748 (0.53%)	1/480 (0.21%)
CARDIOMYOPATHY [A] †	0/748 (0%)	1/480 (0.21%)
CARDIOPULMONARY FAILURE [A] †	4/748 (0.53%)	1/480 (0.21%)
CARDIOVASCULAR DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
CONGESTIVE CARDIOMYOPATHY [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
COR PULMONALE [A] †	2/748 (0.27%)	0/480 (0%)
CORONARY ARTERY DISEASE [A] †	9/748 (1.2%)	9/480 (1.88%)
CORONARY ARTERY DISSECTION [A] †	1/748 (0.13%)	0/480 (0%)
CORONARY ARTERY OCCLUSION [A] †	1/748 (0.13%)	1/480 (0.21%)
CORONARY ARTERY STENOSIS [A] †	1/748 (0.13%)	3/480 (0.63%)
ELECTROMECHANICAL DISSOCIATION [A] †	0/748 (0%)	1/480 (0.21%)
HYPERTENSIVE CARDIOMYOPATHY [A] †	0/748 (0%)	1/480 (0.21%)
HYPERTENSIVE HEART DISEASE [A] †	1/748 (0.13%)	0/480 (0%)
HYPERTROPHIC CARDIOMYOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
ISCHAEMIC CARDIOMYOPATHY [A] †	2/748 (0.27%)	0/480 (0%)
LEFT VENTRICULAR FAILURE [A] †	2/748 (0.27%)	1/480 (0.21%)
LEFT VENTRICULAR HYPERTROPHY [A] †	1/748 (0.13%)	0/480 (0%)
MITRAL VALVE INCOMPETENCE [A] †	1/748 (0.13%)	2/480 (0.42%)
MYOCARDIAL INFARCTION [A] †	27/748 (3.61%)	15/480 (3.12%)
MYOCARDIAL ISCHAEMIA [A] †	7/748 (0.94%)	4/480 (0.83%)
NODAL ARRHYTHMIA [A] †	1/748 (0.13%)	0/480 (0%)
PALPITATIONS [A] †	1/748 (0.13%)	1/480 (0.21%)
PERICARDIAL DISEASE [A] †	0/748 (0%)	1/480 (0.21%)
PERICARDIAL EFFUSION [A] †	1/748 (0.13%)	0/480 (0%)
PERICARDITIS [A] †	3/748 (0.4%)	1/480 (0.21%)
SICK SINUS SYNDROME [A] †	1/748 (0.13%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
SINUS ARRHYTHMIA [A] †	1/748 (0.13%)	0/480 (0%)
SUPRAVENTRICULAR TACHYCARDIA [A] †	2/748 (0.27%)	1/480 (0.21%)
TACHYARRHYTHMIA [A] †	1/748 (0.13%)	0/480 (0%)
TACHYCARDIA [A] †	2/748 (0.27%)	1/480 (0.21%)
VENTRICULAR ARRHYTHMIA [A] †	1/748 (0.13%)	0/480 (0%)
VENTRICULAR EXTRASYSTOLES [A] †	0/748 (0%)	1/480 (0.21%)
VENTRICULAR FIBRILLATION [A] †	6/748 (0.8%)	4/480 (0.83%)
VENTRICULAR HYPERTROPHY [A] †	1/748 (0.13%)	0/480 (0%)
VENTRICULAR TACHYCARDIA [A] †	3/748 (0.4%)	1/480 (0.21%)
Congenital, familial and genetic disorders		
CONGENITAL CYSTIC KIDNEY DISEASE [A] †	1/748 (0.13%)	0/480 (0%)
GASTROINTESTINAL ANGIODYSPLASIA HAEMORRHAGIC [A] †	2/748 (0.27%)	0/480 (0%)
Ear and labyrinth disorders		
VERTIGO [A] †	0/748 (0%)	2/480 (0.42%)
VERTIGO POSITIONAL [A] †	0/748 (0%)	1/480 (0.21%)
Endocrine disorders		
GOITRE [A] †	1/748 (0.13%)	0/480 (0%)
HYPERPARATHYROIDISM [A] †	1/748 (0.13%)	2/480 (0.42%)
HYPERPARATHYROIDISM SECONDARY [A] †	15/748 (2.01%)	6/480 (1.25%)
HYPERPARATHYROIDISM TERTIARY [A] †	2/748 (0.27%)	2/480 (0.42%)
HYPERTHYROIDISM [A] †	1/748 (0.13%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
Eye disorders		
CATARACT [A] †	3/748 (0.4%)	4/480 (0.83%)
CONJUNCTIVAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
GLAUCOMA [A] †	1/748 (0.13%)	0/480 (0%)
RETINAL DETACHMENT [A] †	0/748 (0%)	1/480 (0.21%)
Gastrointestinal disorders		
ABDOMINAL HERNIA [A] †	2/748 (0.27%)	1/480 (0.21%)
ABDOMINAL HERNIA OBSTRUCTIVE [A] †	1/748 (0.13%)	0/480 (0%)
ABDOMINAL PAIN [A] †	4/748 (0.53%)	2/480 (0.42%)
ABDOMINAL PAIN UPPER [A] †	0/748 (0%)	1/480 (0.21%)
ABDOMINAL STRANGULATED HERNIA [A] †	2/748 (0.27%)	0/480 (0%)
ACUTE ABDOMEN [A] †	0/748 (0%)	1/480 (0.21%)
ASCITES [A] †	1/748 (0.13%)	0/480 (0%)
CAECITIS [A] †	0/748 (0%)	2/480 (0.42%)
COLITIS [A] †	3/748 (0.4%)	1/480 (0.21%)
COLITIS ISCHAEMIC [A] †	5/748 (0.67%)	0/480 (0%)
COLONIC POLYP [A] †	3/748 (0.4%)	1/480 (0.21%)
CONSTIPATION [A] †	2/748 (0.27%)	4/480 (0.83%)
DIARRHOEA [A] †	7/748 (0.94%)	4/480 (0.83%)
DIVERTICULAR PERFORATION [A] †	1/748 (0.13%)	2/480 (0.42%)
DIVERTICULITIS INTESTINAL HAEMORRHAGIC [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
DIVERTICULUM [A] †	0/748 (0%)	2/480 (0.42%)
DIVERTICULUM INTESTINAL [A] †	2/748 (0.27%)	0/480 (0%)
DIVERTICULUM INTESTINAL HAEMORRHAGIC [A] †	4/748 (0.53%)	2/480 (0.42%)
DUODENAL OBSTRUCTION [A] †	1/748 (0.13%)	0/480 (0%)
DUODENAL ULCER [A] †	1/748 (0.13%)	1/480 (0.21%)
DUODENAL ULCER HAEMORRHAGE [A] †	2/748 (0.27%)	1/480 (0.21%)
DUODENAL ULCER PERFORATION [A] †	1/748 (0.13%)	0/480 (0%)
DUODENITIS [A] †	3/748 (0.4%)	0/480 (0%)
DUODENITIS HAEMORRHAGIC [A] †	1/748 (0.13%)	0/480 (0%)
DYSPHAGIA [A] †	1/748 (0.13%)	0/480 (0%)
EROSIVE DUODENITIS [A] †	0/748 (0%)	1/480 (0.21%)
EROSIVE OESOPHAGITIS [A] †	1/748 (0.13%)	0/480 (0%)
FLATULENCE [A] †	0/748 (0%)	1/480 (0.21%)
GASTRIC DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
GASTRIC ULCER HAEMORRHAGE [A] †	4/748 (0.53%)	2/480 (0.42%)
GASTRITIS [A] †	9/748 (1.2%)	3/480 (0.63%)
GASTRITIS EROSIVE [A] †	1/748 (0.13%)	0/480 (0%)
GASTRITIS HAEMORRHAGIC [A] †	2/748 (0.27%)	0/480 (0%)
GASTRODUODENITIS [A] †	1/748 (0.13%)	0/480 (0%)
GASTROINTESTINAL DISORDER [A] †	0/748 (0%)	1/480 (0.21%)
GASTROINTESTINAL HAEMORRHAGE [A] †	8/748 (1.07%)	8/480 (1.67%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
GASTROINTESTINAL OBSTRUCTION [A] †	0/748 (0%)	1/480 (0.21%)
GASTROINTESTINAL TELANGIECTASIA [A] †	0/748 (0%)	1/480 (0.21%)
GASTROINTESTINAL ULCER HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
GASTROOESOPHAGEAL REFLUX DISEASE [A] †	3/748 (0.4%)	0/480 (0%)
HAEMATEMESIS [A] †	0/748 (0%)	1/480 (0.21%)
HAEMORRHOIDS [A] †	0/748 (0%)	3/480 (0.63%)
ILEUS [A] †	2/748 (0.27%)	1/480 (0.21%)
ILEUS PARALYTIC [A] †	1/748 (0.13%)	0/480 (0%)
INGUINAL HERNIA [A] †	1/748 (0.13%)	2/480 (0.42%)
INTESTINAL INFARCTION [A] †	2/748 (0.27%)	2/480 (0.42%)
INTESTINAL ISCHAEMIA [A] †	2/748 (0.27%)	1/480 (0.21%)
INTESTINAL OBSTRUCTION [A] †	1/748 (0.13%)	1/480 (0.21%)
INTESTINAL PERFORATION [A] †	1/748 (0.13%)	0/480 (0%)
IRRITABLE BOWEL SYNDROME [A] †	1/748 (0.13%)	0/480 (0%)
LARGE INTESTINAL HAEMORRHAGE [A] †	1/748 (0.13%)	1/480 (0.21%)
LOWER GASTROINTESTINAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
MEGACOLON [A] †	1/748 (0.13%)	0/480 (0%)
MELAENA [A] †	2/748 (0.27%)	2/480 (0.42%)
PANCREATITIS [A] †	8/748 (1.07%)	2/480 (0.42%)
PANCREATITIS ACUTE [A] †	1/748 (0.13%)	2/480 (0.42%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
PANCREATITIS CHRONIC [A] †	1/748 (0.13%)	1/480 (0.21%)
PEPTIC ULCER [A] †	1/748 (0.13%)	0/480 (0%)
PERITONITIS [A] †	8/748 (1.07%)	6/480 (1.25%)
RECTAL HAEMORRHAGE [A] †	2/748 (0.27%)	1/480 (0.21%)
REFLUX OESOPHAGITIS [A] †	2/748 (0.27%)	0/480 (0%)
RETROPERITONEAL FIBROSIS [A] †	0/748 (0%)	1/480 (0.21%)
RETROPERITONEAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
SMALL INTESTINAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
SMALL INTESTINAL OBSTRUCTION [A] †	3/748 (0.4%)	2/480 (0.42%)
SUBILEUS [A] †	1/748 (0.13%)	1/480 (0.21%)
UPPER GASTROINTESTINAL HAEMORRHAGE [A] †	5/748 (0.67%)	2/480 (0.42%)
VOMITING [A] †	4/748 (0.53%)	2/480 (0.42%)
General disorders		
ASTHENIA [A] †	2/748 (0.27%)	1/480 (0.21%)
CALCINOSIS [A] †	1/748 (0.13%)	0/480 (0%)
CATHETER RELATED COMPLICATION [A] †	2/748 (0.27%)	3/480 (0.63%)
CATHETER SITE HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
CATHETER THROMBOSIS [A] †	3/748 (0.4%)	4/480 (0.83%)
CHEST DISCOMFORT [A] †	1/748 (0.13%)	0/480 (0%)
CHEST PAIN [A] †	2/748 (0.27%)	2/480 (0.42%)
CHILLS [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
DEATH [A] †	7/748 (0.94%)	8/480 (1.67%)
GENERAL PHYSICAL HEALTH DETERIORATION [A] †	3/748 (0.4%)	0/480 (0%)
HERNIA OBSTRUCTIVE [A] †	2/748 (0.27%)	0/480 (0%)
HYPERPYREXIA [A] †	3/748 (0.4%)	0/480 (0%)
HYPERTHERMIA [A] †	1/748 (0.13%)	1/480 (0.21%)
IMPAIRED HEALING [A] †	0/748 (0%)	1/480 (0.21%)
IMPLANT SITE NECROSIS [A] †	0/748 (0%)	1/480 (0.21%)
INFLAMMATION [A] †	0/748 (0%)	1/480 (0.21%)
MULTI-ORGAN DISORDER [A] †	0/748 (0%)	1/480 (0.21%)
MULTI-ORGAN FAILURE [A] †	2/748 (0.27%)	2/480 (0.42%)
NON-CARDIAC CHEST PAIN [A] †	9/748 (1.2%)	4/480 (0.83%)
OEDEMA DUE TO RENAL DISEASE [A] †	0/748 (0%)	1/480 (0.21%)
PAIN [A] †	1/748 (0.13%)	0/480 (0%)
PSEUDOCYST [A] †	0/748 (0%)	1/480 (0.21%)
PYREXIA [A] †	10/748 (1.34%)	5/480 (1.04%)
SUDDEN CARDIAC DEATH [A] †	2/748 (0.27%)	0/480 (0%)
SUDDEN DEATH [A] †	2/748 (0.27%)	4/480 (0.83%)
VESSEL PUNCTURE SITE HAEMATOMA [A] †	2/748 (0.27%)	0/480 (0%)
Hepatobiliary disorders		
BILE DUCT OBSTRUCTION [A] †	1/748 (0.13%)	0/480 (0%)
BILE DUCT STENOSIS [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
BILE DUCT STONE [A] †	1/748 (0.13%)	0/480 (0%)
CHOLECYSTITIS [A] †	4/748 (0.53%)	1/480 (0.21%)
CHOLECYSTITIS ACUTE [A] †	3/748 (0.4%)	1/480 (0.21%)
CHOLELITHIASIS [A] †	7/748 (0.94%)	2/480 (0.42%)
GALLBLADDER POLYP [A] †	1/748 (0.13%)	0/480 (0%)
HEPATIC CIRRHOSIS [A] †	1/748 (0.13%)	0/480 (0%)
HEPATIC CONGESTION [A] †	1/748 (0.13%)	0/480 (0%)
HEPATIC FIBROSIS [A] †	1/748 (0.13%)	0/480 (0%)
HEPATITIS [A] †	1/748 (0.13%)	0/480 (0%)
HEPATOSPLENOMEGALY [A] †	0/748 (0%)	1/480 (0.21%)
JAUNDICE CHOLESTATIC [A] †	1/748 (0.13%)	0/480 (0%)
Immune system disorders		
ANAPHYLACTIC REACTION [A] †	1/748 (0.13%)	0/480 (0%)
ANAPHYLACTOID REACTION [A] †	0/748 (0%)	1/480 (0.21%)
CONTRAST MEDIA ALLERGY [A] †	0/748 (0%)	1/480 (0.21%)
DRUG HYPERSENSITIVITY [A] †	1/748 (0.13%)	0/480 (0%)
KIDNEY TRANSPLANT REJECTION [A] †	0/748 (0%)	3/480 (0.63%)
Infections and infestations		
ABDOMINAL SEPSIS [A] †	0/748 (0%)	1/480 (0.21%)
ABDOMINAL WALL ABSCESS [A] †	1/748 (0.13%)	1/480 (0.21%)
ABSCESS LIMB [A] †	1/748 (0.13%)	1/480 (0.21%)
ANOGENITAL WARTS [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
APPENDICITIS [A] †	4/748 (0.53%)	1/480 (0.21%)
ARTERIOSCLEROTIC GANGRENE [A] †	0/748 (0%)	1/480 (0.21%)
ARTERIOVENOUS FISTULA SITE INFECTION [A] †	1/748 (0.13%)	4/480 (0.83%)
ARTERIOVENOUS GRAFT SITE INFECTION [A] †	7/748 (0.94%)	5/480 (1.04%)
ARTERITIS INFECTIVE [A] †	0/748 (0%)	1/480 (0.21%)
ARTHRITIS BACTERIAL [A] †	0/748 (0%)	1/480 (0.21%)
ARTHRITIS INFECTIVE [A] †	0/748 (0%)	1/480 (0.21%)
BACTERAEMIA [A] †	2/748 (0.27%)	1/480 (0.21%)
BACTERIAL DIARRHOEA [A] †	0/748 (0%)	1/480 (0.21%)
BACTERIAL INFECTION [A] †	2/748 (0.27%)	0/480 (0%)
BACTERIAL SEPSIS [A] †	1/748 (0.13%)	1/480 (0.21%)
BALANOPOSTHITIS INFECTIVE [A] †	1/748 (0.13%)	0/480 (0%)
BRONCHITIS [A] †	10/748 (1.34%)	8/480 (1.67%)
BRONCHOPNEUMONIA [A] †	6/748 (0.8%)	5/480 (1.04%)
CATHETER BACTERAEMIA [A] †	3/748 (0.4%)	0/480 (0%)
CATHETER RELATED INFECTION [A] †	8/748 (1.07%)	3/480 (0.63%)
CATHETER SEPSIS [A] †	7/748 (0.94%)	6/480 (1.25%)
CATHETER SITE INFECTION [A] †	2/748 (0.27%)	0/480 (0%)
CELLULITIS [A] †	15/748 (2.01%)	7/480 (1.46%)
CELLULITIS GANGRENOUS [A] †	2/748 (0.27%)	0/480 (0%)
CELLULITIS OF MALE EXTERNAL [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
CENTRAL LINE INFECTION [A] †	4/748 (0.53%)	2/480 (0.42%)
CHOLECYSTITIS INFECTIVE [A] †	2/748 (0.27%)	1/480 (0.21%)
CHRONIC TONSILLITIS [A] †	0/748 (0%)	1/480 (0.21%)
CLOSTRIDIUM DIFFICILE COLITIS [A] †	5/748 (0.67%)	4/480 (0.83%)
CYSTITIS [A] †	0/748 (0%)	1/480 (0.21%)
DIABETIC FOOT INFECTION [A] †	1/748 (0.13%)	2/480 (0.42%)
DIABETIC GANGRENE [A] †	5/748 (0.67%)	2/480 (0.42%)
DISSEMINATED TUBERCULOSIS [A] †	0/748 (0%)	1/480 (0.21%)
DIVERTICULITIS [A] †	6/748 (0.8%)	1/480 (0.21%)
EMPHYSEMATOUS CHOLECYSTITIS [A] †	1/748 (0.13%)	0/480 (0%)
EMPYEMA [A] †	1/748 (0.13%)	0/480 (0%)
ENDOCARDITIS [A] †	3/748 (0.4%)	2/480 (0.42%)
ENDOCARDITIS STAPHYLOCOCCAL [A] †	1/748 (0.13%)	0/480 (0%)
ENTEROCOCCAL SEPSIS [A] †	0/748 (0%)	1/480 (0.21%)
ERYSIPELAS [A] †	0/748 (0%)	2/480 (0.42%)
ESCHERICHIA SEPSIS [A] †	1/748 (0.13%)	0/480 (0%)
ESCHERICHIA URINARY TRACT INFECTION [A] †	1/748 (0.13%)	0/480 (0%)
EYE INFECTION STAPHYLOCOCCAL [A] †	1/748 (0.13%)	0/480 (0%)
FUNGAEMIA [A] †	2/748 (0.27%)	0/480 (0%)
FUNGAL PERITONITIS [A] †	0/748 (0%)	1/480 (0.21%)
GANGRENE [A] †	7/748 (0.94%)	5/480 (1.04%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
GASTRIC ULCER HELICOBACTER [A] †	0/748 (0%)	1/480 (0.21%)
GASTROENTERITIS [A] †	11/748 (1.47%)	4/480 (0.83%)
GASTROENTERITIS VIRAL [A] †	5/748 (0.67%)	3/480 (0.63%)
GENITAL ORGAN CELLULITIS STREPTOCOCCAL [A] †	1/748 (0.13%)	0/480 (0%)
GRAFT INFECTION [A] †	1/748 (0.13%)	1/480 (0.21%)
GROIN ABSCESS [A] †	1/748 (0.13%)	1/480 (0.21%)
HAEMATOMA INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
HEPATITIS C [A] †	1/748 (0.13%)	0/480 (0%)
INFECTED BITES [A] †	1/748 (0.13%)	0/480 (0%)
INFECTED CYST [A] †	1/748 (0.13%)	0/480 (0%)
INFECTED SKIN ULCER [A] †	4/748 (0.53%)	0/480 (0%)
INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE [A] †	0/748 (0%)	1/480 (0.21%)
INFLUENZA [A] †	1/748 (0.13%)	0/480 (0%)
INTERVERTEBRAL DISCITIS [A] †	2/748 (0.27%)	1/480 (0.21%)
KLEBSIELLA SEPSIS [A] †	1/748 (0.13%)	0/480 (0%)
LIVER ABSCESS [A] †	1/748 (0.13%)	0/480 (0%)
LOBAR PNEUMONIA [A] †	0/748 (0%)	1/480 (0.21%)
LOCALISED INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
LOWER RESPIRATORY TRACT INFECTION [A] †	4/748 (0.53%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
LUNG INFECTION [A] †	2/748 (0.27%)	1/480 (0.21%)
NOSOCOMIAL INFECTION [A] †	1/748 (0.13%)	0/480 (0%)
ORAL INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
OSTEOMYELITIS [A] †	5/748 (0.67%)	3/480 (0.63%)
OSTEOMYELITIS CHRONIC [A] †	0/748 (0%)	1/480 (0.21%)
PANCREAS INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
PAROTID ABSCESS [A] †	1/748 (0.13%)	0/480 (0%)
PERITONITIS BACTERIAL [A] †	1/748 (0.13%)	3/480 (0.63%)
PHARYNGEAL ABSCESS [A] †	1/748 (0.13%)	0/480 (0%)
PHARYNGITIS [A] †	1/748 (0.13%)	0/480 (0%)
PNEUMOCOCCAL SEPSIS [A] †	1/748 (0.13%)	0/480 (0%)
PNEUMONIA [A] †	53/748 (7.09%)	35/480 (7.29%)
PNEUMONIA BACTERIAL [A] †	1/748 (0.13%)	0/480 (0%)
PNEUMONIA KLEBSIELLA [A] †	1/748 (0.13%)	0/480 (0%)
PNEUMONIA PRIMARY ATYPICAL [A] †	0/748 (0%)	1/480 (0.21%)
PNEUMONIA STAPHYLOCOCCAL [A] †	2/748 (0.27%)	0/480 (0%)
PNEUMONIA STREPTOCOCCAL [A] †	2/748 (0.27%)	0/480 (0%)
POST PROCEDURAL INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
POST PROCEDURAL SEPSIS [A] †	1/748 (0.13%)	0/480 (0%)
POSTOPERATIVE WOUND INFECTION [A] †	3/748 (0.4%)	2/480 (0.42%)
PSEUDOMEMBRANOUS COLITIS [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
PULMONARY SEPSIS [A] †	0/748 (0%)	1/480 (0.21%)
PULMONARY TUBERCULOSIS [A] †	1/748 (0.13%)	0/480 (0%)
PYELONEPHRITIS [A] †	2/748 (0.27%)	0/480 (0%)
RECTAL ABSCESS [A] †	1/748 (0.13%)	0/480 (0%)
RESPIRATORY TRACT INFECTION [A] †	0/748 (0%)	1/480 (0.21%)
RESPIRATORY TRACT INFECTION VIRAL [A] †	0/748 (0%)	1/480 (0.21%)
SEPSIS [A] †	24/748 (3.21%)	12/480 (2.5%)
SEPTIC ARTHRITIS STAPHYLOCOCCAL [A] †	1/748 (0.13%)	0/480 (0%)
SEPTIC SHOCK [A] †	8/748 (1.07%)	4/480 (0.83%)
SERRATIA BACTERAEMIA [A] †	1/748 (0.13%)	0/480 (0%)
SERRATIA INFECTION [A] †	1/748 (0.13%)	0/480 (0%)
STAPHYLOCOCCAL ABSCESS [A] †	1/748 (0.13%)	0/480 (0%)
STAPHYLOCOCCAL BACTERAEMIA [A] †	6/748 (0.8%)	3/480 (0.63%)
STAPHYLOCOCCAL INFECTION [A] †	1/748 (0.13%)	1/480 (0.21%)
STAPHYLOCOCCAL OSTEOMYELITIS [A] †	1/748 (0.13%)	0/480 (0%)
STAPHYLOCOCCAL SEPSIS [A] †	6/748 (0.8%)	4/480 (0.83%)
STREPTOCOCCAL SEPSIS [A] †	1/748 (0.13%)	1/480 (0.21%)
SUBCUTANEOUS ABSCESS [A] †	0/748 (0%)	1/480 (0.21%)
TUBERCULOSIS [A] †	1/748 (0.13%)	0/480 (0%)
TUBERCULOUS PLEURISY [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
UPPER RESPIRATORY TRACT INFECTION [A] †	4/748 (0.53%)	2/480 (0.42%)
URINARY TRACT INFECTION [A] †	7/748 (0.94%)	4/480 (0.83%)
UROSEPSIS [A] †	4/748 (0.53%)	1/480 (0.21%)
VIRAL INFECTION [A] †	1/748 (0.13%)	1/480 (0.21%)
WEST NILE VIRAL INFECTION [A] †	1/748 (0.13%)	0/480 (0%)
WOUND INFECTION [A] †	3/748 (0.4%)	1/480 (0.21%)
Injury, poisoning and procedural complications		
ACETABULUM FRACTURE [A] †	1/748 (0.13%)	0/480 (0%)
ALCOHOL POISONING [A] †	1/748 (0.13%)	0/480 (0%)
ANAEMIA POSTOPERATIVE [A] †	2/748 (0.27%)	0/480 (0%)
ANKLE FRACTURE [A] †	0/748 (0%)	2/480 (0.42%)
ARTERIOVENOUS FISTULA ANEURYSM [A] †	4/748 (0.53%)	3/480 (0.63%)
ARTERIOVENOUS FISTULA OCCLUSION [A] †	0/748 (0%)	1/480 (0.21%)
ARTERIOVENOUS FISTULA SITE COMPLICATION [A] †	6/748 (0.8%)	9/480 (1.88%)
ARTERIOVENOUS FISTULA SITE HAEMATOMA [A] †	0/748 (0%)	1/480 (0.21%)
ARTERIOVENOUS FISTULA SITE HAEMORRHAGE [A] †	7/748 (0.94%)	4/480 (0.83%)
ARTERIOVENOUS FISTULA THROMBOSIS [A] †	26/748 (3.48%)	20/480 (4.17%)
ARTERIOVENOUS GRAFT ANEURYSM [A] †	0/748 (0%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
ARTERIOVENOUS GRAFT SITE HAEMORRHAGE [A] †	3/748 (0.4%)	1/480 (0.21%)
ARTERIOVENOUS GRAFT THROMBOSIS [A] †	16/748 (2.14%)	8/480 (1.67%)
CHEST INJURY [A] †	1/748 (0.13%)	0/480 (0%)
CLAVICLE FRACTURE [A] †	1/748 (0.13%)	0/480 (0%)
CONCUSSION [A] †	2/748 (0.27%)	0/480 (0%)
CONTUSION [A] †	1/748 (0.13%)	0/480 (0%)
DELAYED RECOVERY FROM ANAESTHESIA [A] †	0/748 (0%)	1/480 (0.21%)
DEVICE MALFUNCTION [A] †	0/748 (0%)	1/480 (0.21%)
DIALYSIS DEVICE COMPLICATION [A] †	1/748 (0.13%)	0/480 (0%)
DISLOCATION OF JOINT PROSTHESIS [A] †	1/748 (0.13%)	0/480 (0%)
FACIAL BONES FRACTURE [A] †	1/748 (0.13%)	1/480 (0.21%)
FALL [A] †	0/748 (0%)	1/480 (0.21%)
FEMORAL NECK FRACTURE [A] †	11/748 (1.47%)	3/480 (0.63%)
FEMUR FRACTURE [A] †	5/748 (0.67%)	4/480 (0.83%)
FIBULA FRACTURE [A] †	1/748 (0.13%)	1/480 (0.21%)
FOOT FRACTURE [A] †	0/748 (0%)	1/480 (0.21%)
FOREARM FRACTURE [A] †	1/748 (0.13%)	0/480 (0%)
FRACTURED COCCYX [A] †	0/748 (0%)	1/480 (0.21%)
GRAFT THROMBOSIS [A] †	1/748 (0.13%)	2/480 (0.42%)
HEAD INJURY [A] †	2/748 (0.27%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
HEPATIC HAEMATOMA [A] †	1/748 (0.13%)	0/480 (0%)
HIP FRACTURE [A] †	5/748 (0.67%)	3/480 (0.63%)
HUMERUS FRACTURE [A] †	2/748 (0.27%)	0/480 (0%)
IN-STENT CORONARY ARTERY RESTENOSIS [A] †	0/748 (0%)	2/480 (0.42%)
INCISIONAL HERNIA [A] †	2/748 (0.27%)	1/480 (0.21%)
JOINT DISLOCATION [A] †	0/748 (0%)	1/480 (0.21%)
JOINT INJURY [A] †	2/748 (0.27%)	0/480 (0%)
LOWER LIMB FRACTURE [A] †	2/748 (0.27%)	0/480 (0%)
LUMBAR VERTEBRAL FRACTURE [A] †	1/748 (0.13%)	0/480 (0%)
MULTIPLE FRACTURES [A] †	2/748 (0.27%)	0/480 (0%)
MUSCLE RUPTURE [A] †	1/748 (0.13%)	0/480 (0%)
OVERDOSE [A] †	2/748 (0.27%)	1/480 (0.21%)
PELVIC FRACTURE [A] †	2/748 (0.27%)	3/480 (0.63%)
PERIORBITAL HAEMATOMA [A] †	0/748 (0%)	1/480 (0.21%)
PERIRENAL HAEMATOMA [A] †	1/748 (0.13%)	0/480 (0%)
PNEUMOTHORAX TRAUMATIC [A] †	1/748 (0.13%)	1/480 (0.21%)
POST PROCEDURAL COMPLICATION [A] †	0/748 (0%)	2/480 (0.42%)
POST PROCEDURAL HAEMATOMA [A] †	5/748 (0.67%)	2/480 (0.42%)
POST PROCEDURAL HAEMORRHAGE [A] †	7/748 (0.94%)	2/480 (0.42%)
POST PROCEDURAL MYOCARDIAL INFARCTION [A] †	0/748 (0%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
POST PROCEDURAL PULMONARY EMBOLISM [A] †	0/748 (0%)	1/480 (0.21%)
POSTOPERATIVE FEVER [A] †	0/748 (0%)	1/480 (0.21%)
POSTOPERATIVE WOUND COMPLICATION [A] †	0/748 (0%)	1/480 (0.21%)
POSTPERICARDIOTOMY SYNDROME [A] †	1/748 (0.13%)	0/480 (0%)
PROCEDURAL COMPLICATION [A] †	0/748 (0%)	1/480 (0.21%)
PROCEDURAL HYPOTENSION [A] †	9/748 (1.2%)	2/480 (0.42%)
PROCEDURAL PAIN [A] †	1/748 (0.13%)	0/480 (0%)
PROCEDURAL VOMITING [A] †	1/748 (0.13%)	0/480 (0%)
PUBIC RAMI FRACTURE [A] †	2/748 (0.27%)	0/480 (0%)
RADIUS FRACTURE [A] †	2/748 (0.27%)	1/480 (0.21%)
RIB FRACTURE [A] †	0/748 (0%)	2/480 (0.42%)
SKULL FRACTURE [A] †	1/748 (0.13%)	0/480 (0%)
SOFT TISSUE INJURY [A] †	0/748 (0%)	1/480 (0.21%)
SPLENIC RUPTURE [A] †	1/748 (0.13%)	0/480 (0%)
SUBDURAL HAEMATOMA [A] †	3/748 (0.4%)	6/480 (1.25%)
SUBDURAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
SYNOVIAL RUPTURE [A] †	0/748 (0%)	1/480 (0.21%)
TENDON RUPTURE [A] †	2/748 (0.27%)	2/480 (0.42%)
THERAPEUTIC AGENT TOXICITY [A] †	0/748 (0%)	2/480 (0.42%)
TIBIA FRACTURE [A] †	1/748 (0.13%)	1/480 (0.21%)
ULNA FRACTURE [A] †	0/748 (0%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
UPPER LIMB FRACTURE [A] †	0/748 (0%)	1/480 (0.21%)
UROSTOMY COMPLICATION [A] †	1/748 (0.13%)	0/480 (0%)
VASCULAR GRAFT COMPLICATION [A] †	6/748 (0.8%)	4/480 (0.83%)
VASCULAR GRAFT OCCLUSION [A] †	0/748 (0%)	1/480 (0.21%)
VASCULAR PSEUDOANEURYSM [A] †	2/748 (0.27%)	1/480 (0.21%)
WOUND [A] †	1/748 (0.13%)	0/480 (0%)
WRIST FRACTURE [A] †	2/748 (0.27%)	1/480 (0.21%)
Investigations		
BACTERIAL CULTURE POSITIVE [A] †	0/748 (0%)	1/480 (0.21%)
Metabolism and nutrition disorders		
CACHEXIA [A] †	4/748 (0.53%)	5/480 (1.04%)
CALCIPHYLAXIS [A] †	1/748 (0.13%)	1/480 (0.21%)
DEHYDRATION [A] †	3/748 (0.4%)	1/480 (0.21%)
DIABETES MELLITUS [A] †	0/748 (0%)	1/480 (0.21%)
DIABETES MELLITUS INADEQUATE CONTROL [A] †	4/748 (0.53%)	3/480 (0.63%)
DIABETIC FOOT [A] †	3/748 (0.4%)	7/480 (1.46%)
ELECTROLYTE IMBALANCE [A] †	0/748 (0%)	1/480 (0.21%)
FAILURE TO THRIVE [A] †	0/748 (0%)	1/480 (0.21%)
FLUID OVERLOAD [A] †	16/748 (2.14%)	11/480 (2.29%)
FLUID RETENTION [A] †	0/748 (0%)	1/480 (0.21%)
GOUT [A] †	3/748 (0.4%)	0/480 (0%)
HYPERCALCAEMIA [A] †	2/748 (0.27%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
HYPERGLYCAEMIA [A] †	2/748 (0.27%)	2/480 (0.42%)
HYPERKALAEMIA [A] †	15/748 (2.01%)	12/480 (2.5%)
HYPERVOLAEMIA [A] †	1/748 (0.13%)	0/480 (0%)
HYPOCALCAEMIA [A] †	2/748 (0.27%)	3/480 (0.63%)
HYPOGLYCAEMIA [A] †	7/748 (0.94%)	10/480 (2.08%)
HYPONATRAEMIA [A] †	0/748 (0%)	1/480 (0.21%)
HYPOVOLAEMIA [A] †	0/748 (0%)	1/480 (0.21%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA [A] †	0/748 (0%)	2/480 (0.42%)
ARTHRITIS [A] †	2/748 (0.27%)	0/480 (0%)
BACK PAIN [A] †	4/748 (0.53%)	0/480 (0%)
CERVICAL SPINAL STENOSIS [A] †	1/748 (0.13%)	0/480 (0%)
COSTOCHONDRITIS [A] †	1/748 (0.13%)	0/480 (0%)
DACTYLITIS [A] †	1/748 (0.13%)	0/480 (0%)
FASCIITIS [A] †	1/748 (0.13%)	0/480 (0%)
FLANK PAIN [A] †	1/748 (0.13%)	0/480 (0%)
HAEMARTHROSIS [A] †	0/748 (0%)	1/480 (0.21%)
INTERVERTEBRAL DISC DISORDER [A] †	1/748 (0.13%)	1/480 (0.21%)
INTERVERTEBRAL DISC PROTRUSION [A] †	0/748 (0%)	1/480 (0.21%)
MUSCLE HAEMORRHAGE [A] †	0/748 (0%)	1/480 (0.21%)
MUSCULAR WEAKNESS [A] †	1/748 (0.13%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
MUSCULOSKELETAL CHEST PAIN [A] †	1/748 (0.13%)	0/480 (0%)
MUSCULOSKELETAL PAIN [A] †	2/748 (0.27%)	1/480 (0.21%)
MYOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
OSTEITIS [A] †	1/748 (0.13%)	0/480 (0%)
OSTEOARTHRITIS [A] †	4/748 (0.53%)	4/480 (0.83%)
OSTEODYSTROPHY [A] †	1/748 (0.13%)	0/480 (0%)
OSTEOLYSIS [A] †	0/748 (0%)	1/480 (0.21%)
OSTEONECROSIS [A] †	1/748 (0.13%)	0/480 (0%)
OSTEOPOROSIS [A] †	1/748 (0.13%)	0/480 (0%)
PAIN IN EXTREMITY [A] †	1/748 (0.13%)	1/480 (0.21%)
POLYMYALGIA RHEUMATICA [A] †	1/748 (0.13%)	0/480 (0%)
ROTATOR CUFF SYNDROME [A] †	1/748 (0.13%)	0/480 (0%)
SOFT TISSUE NECROSIS [A] †	1/748 (0.13%)	0/480 (0%)
SPINAL COLUMN STENOSIS [A] †	1/748 (0.13%)	0/480 (0%)
SPINAL OSTEOARTHRITIS [A] †	2/748 (0.27%)	2/480 (0.42%)
SYNOVITIS [A] †	1/748 (0.13%)	0/480 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
ADENOID CYSTIC CARCINOMA [A] †	1/748 (0.13%)	0/480 (0%)
BASAL CELL CARCINOMA [A] †	0/748 (0%)	1/480 (0.21%)
BLADDER NEOPLASM [A] †	1/748 (0.13%)	0/480 (0%)
BLADDER TRANSITIONAL CELL CARCINOMA [A] †	2/748 (0.27%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
BREAST CANCER [A] †	2/748 (0.27%)	1/480 (0.21%)
BREAST CANCER IN SITU [A] †	0/748 (0%)	1/480 (0.21%)
BREAST CANCER METASTATIC [A] †	1/748 (0.13%)	0/480 (0%)
CHRONIC LYMPHOCYTIC LEUKAEMIA [A] †	1/748 (0.13%)	0/480 (0%)
COLON ADENOMA [A] †	0/748 (0%)	1/480 (0.21%)
COLON CANCER [A] †	5/748 (0.67%)	2/480 (0.42%)
COLON CANCER METASTATIC [A] †	2/748 (0.27%)	0/480 (0%)
LUNG ADENOCARCINOMA [A] †	1/748 (0.13%)	0/480 (0%)
LUNG CANCER METASTATIC [A] †	0/748 (0%)	3/480 (0.63%)
LUNG NEOPLASM [A] †	2/748 (0.27%)	2/480 (0.42%)
LUNG NEOPLASM MALIGNANT [A] †	3/748 (0.4%)	0/480 (0%)
LUNG SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED [A] †	2/748 (0.27%)	0/480 (0%)
MALIGNANT PLEURAL EFFUSION [A] †	0/748 (0%)	1/480 (0.21%)
METASTASES TO CENTRAL NERVOUS SYSTEM [A] †	1/748 (0.13%)	0/480 (0%)
METASTASES TO LIVER [A] †	1/748 (0.13%)	0/480 (0%)
METASTATIC GASTRIC CANCER [A] †	0/748 (0%)	1/480 (0.21%)
METASTATIC NEOPLASM [A] †	1/748 (0.13%)	1/480 (0.21%)
MULTIPLE MYELOMA [A] †	0/748 (0%)	1/480 (0.21%)
PANCREATIC CARCINOMA METASTATIC [A] †	1/748 (0.13%)	1/480 (0.21%)
PANCREATIC NEOPLASM [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
PARATHYROID TUMOUR [A] †	0/748 (0%)	1/480 (0.21%)
PROSTATE CANCER [A] †	4/748 (0.53%)	1/480 (0.21%)
PROSTATE CANCER METASTATIC [A] †	1/748 (0.13%)	0/480 (0%)
RENAL CANCER [A] †	0/748 (0%)	1/480 (0.21%)
RENAL CELL CARCINOMA [A] †	2/748 (0.27%)	1/480 (0.21%)
RENAL NEOPLASM [A] †	2/748 (0.27%)	0/480 (0%)
RENAL ONCOCYTOMA [A] †	1/748 (0.13%)	0/480 (0%)
SKIN CANCER [A] †	1/748 (0.13%)	0/480 (0%)
SMALL CELL LUNG CANCER METASTATIC [A] †	1/748 (0.13%)	0/480 (0%)
SMALL CELL LUNG CANCER STAGE UNSPECIFIED [A] †	0/748 (0%)	1/480 (0.21%)
SQUAMOUS CELL CARCINOMA OF SKIN [A] †	1/748 (0.13%)	0/480 (0%)
THYROID CANCER [A] †	1/748 (0.13%)	0/480 (0%)
THYROID NEOPLASM [A] †	1/748 (0.13%)	0/480 (0%)
URINARY TRACT NEOPLASM [A] †	1/748 (0.13%)	0/480 (0%)
UTERINE LEIOMYOMA [A] †	0/748 (0%)	1/480 (0.21%)
Nervous system disorders		
ALTERED STATE OF CONSCIOUSNESS [A] †	1/748 (0.13%)	0/480 (0%)
ANOXIC ENCEPHALOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
BALANCE DISORDER [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
BENIGN INTRACRANIAL HYPERTENSION [A] †	1/748 (0.13%)	0/480 (0%)
CAROTID ARTERY STENOSIS [A] †	5/748 (0.67%)	1/480 (0.21%)
CARPAL TUNNEL SYNDROME [A] †	5/748 (0.67%)	1/480 (0.21%)
CEREBRAL ARTERIOSCLEROSIS [A] †	0/748 (0%)	1/480 (0.21%)
CEREBRAL ATROPHY [A] †	1/748 (0.13%)	0/480 (0%)
CEREBRAL HAEMORRHAGE [A] †	8/748 (1.07%)	0/480 (0%)
CEREBRAL INFARCTION [A] †	4/748 (0.53%)	3/480 (0.63%)
CEREBRAL ISCHAEMIA [A] †	3/748 (0.4%)	0/480 (0%)
CEREBROVASCULAR ACCIDENT [A] †	7/748 (0.94%)	8/480 (1.67%)
CEREBROVASCULAR DISORDER [A] †	3/748 (0.4%)	1/480 (0.21%)
CERVICAL MYELOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
COGNITIVE DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
COMA HEPATIC [A] †	1/748 (0.13%)	0/480 (0%)
COMPLEX PARTIAL SEIZURES [A] †	1/748 (0.13%)	0/480 (0%)
CONVULSION [A] †	3/748 (0.4%)	1/480 (0.21%)
DEMENTIA ALZHEIMER'S TYPE [A] †	1/748 (0.13%)	0/480 (0%)
DEMENTIA WITH LEWY BODIES [A] †	1/748 (0.13%)	0/480 (0%)
DIZZINESS [A] †	2/748 (0.27%)	0/480 (0%)
EMBOLIC CEREBRAL INFARCTION [A] †	1/748 (0.13%)	1/480 (0.21%)
EMBOLIC STROKE [A] †	1/748 (0.13%)	1/480 (0.21%)
ENCEPHALOPATHY [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
EPILEPSY [A] †	0/748 (0%)	2/480 (0.42%)
HAEMORRHAGE INTRACRANIAL [A] †	0/748 (0%)	2/480 (0.42%)
HAEMORRHAGIC CEREBRAL INFARCTION [A] †	0/748 (0%)	1/480 (0.21%)
HAEMORRHAGIC STROKE [A] †	4/748 (0.53%)	1/480 (0.21%)
HEADACHE [A] †	1/748 (0.13%)	1/480 (0.21%)
HEPATIC ENCEPHALOPATHY [A] †	0/748 (0%)	1/480 (0.21%)
HYDROCEPHALUS [A] †	0/748 (0%)	1/480 (0.21%)
HYPERTENSIVE ENCEPHALOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
HYPOGLYCAEMIC COMA [A] †	2/748 (0.27%)	0/480 (0%)
HYPOXIC ENCEPHALOPATHY [A] †	1/748 (0.13%)	1/480 (0.21%)
INTRACRANIAL HAEMATOMA [A] †	1/748 (0.13%)	0/480 (0%)
ISCHAEMIC CEREBRAL INFARCTION [A] †	2/748 (0.27%)	1/480 (0.21%)
ISCHAEMIC STROKE [A] †	5/748 (0.67%)	3/480 (0.63%)
LACUNAR INFARCTION [A] †	1/748 (0.13%)	1/480 (0.21%)
LOSS OF CONSCIOUSNESS [A] †	0/748 (0%)	1/480 (0.21%)
METABOLIC ENCEPHALOPATHY [A] †	0/748 (0%)	1/480 (0.21%)
MUSCLE SPASTICITY [A] †	0/748 (0%)	1/480 (0.21%)
NEURALGIA [A] †	1/748 (0.13%)	0/480 (0%)
NEUROTOXICITY [A] †	0/748 (0%)	1/480 (0.21%)
PARKINSON'S DISEASE [A] †	0/748 (0%)	1/480 (0.21%)
PERIPHERAL SENSORIMOTOR NEUROPATHY [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
POLYNEUROPATHY [A] †	1/748 (0.13%)	0/480 (0%)
PRESYNCOPE [A] †	2/748 (0.27%)	1/480 (0.21%)
REVERSIBLE ISCHAEMIC NEUROLOGICAL DEFICIT [A] †	1/748 (0.13%)	1/480 (0.21%)
SENILE DEMENTIA [A] †	0/748 (0%)	1/480 (0.21%)
SPONDYLITIC MYELOPATHY [A] †	1/748 (0.13%)	0/480 (0%)
STUPOR [A] †	1/748 (0.13%)	0/480 (0%)
SUBARACHNOID HAEMORRHAGE [A] †	0/748 (0%)	1/480 (0.21%)
SYNCOPE [A] †	5/748 (0.67%)	2/480 (0.42%)
TRANSIENT ISCHAEMIC ATTACK [A] †	6/748 (0.8%)	6/480 (1.25%)
URAEMIC NEUROPATHY [A] †	2/748 (0.27%)	0/480 (0%)
Psychiatric disorders		
ACUTE PSYCHOSIS [A] †	1/748 (0.13%)	0/480 (0%)
ANXIETY [A] †	2/748 (0.27%)	1/480 (0.21%)
ANXIETY DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
BIPOLAR I DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
COMPLETED SUICIDE [A] †	1/748 (0.13%)	0/480 (0%)
CONFUSIONAL STATE [A] †	3/748 (0.4%)	1/480 (0.21%)
DELIRIUM [A] †	0/748 (0%)	1/480 (0.21%)
DEPRESSION [A] †	1/748 (0.13%)	1/480 (0.21%)
DEPRESSION SUICIDAL [A] †	0/748 (0%)	1/480 (0.21%)
DISORIENTATION [A] †	0/748 (0%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
MAJOR DEPRESSION [A] †	0/748 (0%)	1/480 (0.21%)
MENTAL DISORDER DUE TO A GENERAL MEDICAL CONDITION [A] †	1/748 (0.13%)	0/480 (0%)
MENTAL STATUS CHANGES [A] †	4/748 (0.53%)	5/480 (1.04%)
PSYCHOTIC DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
SUICIDE ATTEMPT [A] †	0/748 (0%)	1/480 (0.21%)
Renal and urinary disorders		
AZOTAEMIA [A] †	2/748 (0.27%)	1/480 (0.21%)
CALCULUS URETERIC [A] †	0/748 (0%)	2/480 (0.42%)
CYSTITIS HAEMORRHAGIC [A] †	1/748 (0.13%)	1/480 (0.21%)
HAEMATURIA [A] †	1/748 (0.13%)	3/480 (0.63%)
NEPHROLITHIASIS [A] †	1/748 (0.13%)	1/480 (0.21%)
NEPHROPATHY TOXIC [A] †	1/748 (0.13%)	0/480 (0%)
OBSTRUCTIVE UROPATHY [A] †	1/748 (0.13%)	0/480 (0%)
PYELOCALIECTASIS [A] †	0/748 (0%)	1/480 (0.21%)
RENAL CYST RUPTURED [A] †	1/748 (0.13%)	0/480 (0%)
RENAL DISORDER [A] †	0/748 (0%)	1/480 (0.21%)
RENAL FAILURE [A] †	1/748 (0.13%)	1/480 (0.21%)
RENAL FAILURE ACUTE [A] †	4/748 (0.53%)	1/480 (0.21%)
RENAL FAILURE CHRONIC [A] †	22/748 (2.94%)	15/480 (3.12%)
RENAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
RENAL HYPERTENSION [A] †	0/748 (0%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
RENAL IMPAIRMENT [A] †	2/748 (0.27%)	0/480 (0%)
RENAL TUBULAR NECROSIS [A] †	0/748 (0%)	1/480 (0.21%)
URINARY BLADDER POLYP [A] †	1/748 (0.13%)	0/480 (0%)
Reproductive system and breast disorders		
BENIGN PROSTATIC HYPERPLASIA [A] †	1/748 (0.13%)	0/480 (0%)
CERVIX INFLAMMATION [A] †	0/748 (0%)	1/480 (0.21%)
CYSTOCELE [A] †	1/748 (0.13%)	0/480 (0%)
GENITAL PROLAPSE [A] †	0/748 (0%)	1/480 (0.21%)
OVARIAN CYST [A] †	0/748 (0%)	1/480 (0.21%)
PROSTATISM [A] †	1/748 (0.13%)	0/480 (0%)
PROSTATITIS [A] †	0/748 (0%)	1/480 (0.21%)
TESTICULAR INFARCTION [A] †	0/748 (0%)	1/480 (0.21%)
UTERINE CERVICAL SQUAMOUS METAPLASIA [A] †	0/748 (0%)	1/480 (0.21%)
Respiratory, thoracic and mediastinal disorders		
ACUTE PULMONARY OEDEMA [A] †	3/748 (0.4%)	3/480 (0.63%)
ACUTE RESPIRATORY FAILURE [A] †	4/748 (0.53%)	0/480 (0%)
ASTHMA [A] †	1/748 (0.13%)	2/480 (0.42%)
ATELECTASIS [A] †	1/748 (0.13%)	0/480 (0%)
BRONCHITIS CHRONIC [A] †	2/748 (0.27%)	0/480 (0%)
BRONCHOSPASM [A] †	1/748 (0.13%)	0/480 (0%)
CHOKING [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE [A] †	6/748 (0.8%)	5/480 (1.04%)
COUGH [A] †	1/748 (0.13%)	0/480 (0%)
DYSPNOEA [A] †	5/748 (0.67%)	3/480 (0.63%)
EMPHYSEMA [A] †	1/748 (0.13%)	0/480 (0%)
EPISTAXIS [A] †	2/748 (0.27%)	1/480 (0.21%)
HAEMOTHORAX [A] †	2/748 (0.27%)	1/480 (0.21%)
HYDROTHORAX [A] †	0/748 (0%)	1/480 (0.21%)
HYPOXIA [A] †	1/748 (0.13%)	1/480 (0.21%)
LUNG INFILTRATION [A] †	2/748 (0.27%)	0/480 (0%)
MEDIASTINAL HAEMORRHAGE [A] †	1/748 (0.13%)	0/480 (0%)
NON-CARDIOGENIC PULMONARY OEDEMA [A] †	2/748 (0.27%)	2/480 (0.42%)
PLEURAL EFFUSION [A] †	10/748 (1.34%)	7/480 (1.46%)
PLEURITIC PAIN [A] †	1/748 (0.13%)	0/480 (0%)
PNEUMONIA ASPIRATION [A] †	5/748 (0.67%)	2/480 (0.42%)
PNEUMONITIS [A] †	1/748 (0.13%)	0/480 (0%)
PULMONARY EMBOLISM [A] †	5/748 (0.67%)	1/480 (0.21%)
PULMONARY FIBROSIS [A] †	1/748 (0.13%)	0/480 (0%)
PULMONARY GRANULOMA [A] †	1/748 (0.13%)	0/480 (0%)
PULMONARY HAEMORRHAGE [A] †	0/748 (0%)	1/480 (0.21%)
PULMONARY HYPERTENSION [A] †	3/748 (0.4%)	1/480 (0.21%)
PULMONARY OEDEMA [A] †	9/748 (1.2%)	12/480 (2.5%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
PULMONARY VASCULITIS [A] †	1/748 (0.13%)	0/480 (0%)
RESPIRATORY DISTRESS [A] †	0/748 (0%)	1/480 (0.21%)
RESPIRATORY FAILURE [A] †	6/748 (0.8%)	2/480 (0.42%)
TRACHEAL ULCER [A] †	0/748 (0%)	1/480 (0.21%)
UPPER RESPIRATORY TRACT INFLAMMATION [A] †	1/748 (0.13%)	0/480 (0%)
WEGENER'S GRANULOMATOSIS [A] †	1/748 (0.13%)	0/480 (0%)
Skin and subcutaneous tissue disorders		
ANGIOEDEMA [A] †	3/748 (0.4%)	0/480 (0%)
DECUBITUS ULCER [A] †	2/748 (0.27%)	0/480 (0%)
DERMATITIS [A] †	1/748 (0.13%)	0/480 (0%)
DIABETIC NEUROPATHIC ULCER [A] †	0/748 (0%)	1/480 (0.21%)
DRUG ERUPTION [A] †	1/748 (0.13%)	0/480 (0%)
DRY GANGRENE [A] †	2/748 (0.27%)	0/480 (0%)
LIPODYSTROPHY ACQUIRED [A] †	0/748 (0%)	1/480 (0.21%)
PENILE ULCERATION [A] †	0/748 (0%)	1/480 (0.21%)
SKIN DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
SKIN FISSURES [A] †	1/748 (0.13%)	0/480 (0%)
SKIN ULCER [A] †	9/748 (1.2%)	3/480 (0.63%)
Vascular disorders		
ACCELERATED HYPERTENSION [A] †	2/748 (0.27%)	0/480 (0%)
ANEURYSM [A] †	0/748 (0%)	1/480 (0.21%)
ANEURYSM RUPTURED [A] †	0/748 (0%)	1/480 (0.21%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
ANGIOPATHY [A] †	0/748 (0%)	1/480 (0.21%)
AORTIC ANEURYSM [A] †	1/748 (0.13%)	0/480 (0%)
AORTIC ANEURYSM RUPTURE [A] †	3/748 (0.4%)	0/480 (0%)
AORTIC DISSECTION [A] †	0/748 (0%)	1/480 (0.21%)
AORTIC STENOSIS [A] †	1/748 (0.13%)	1/480 (0.21%)
ARTERIAL DISORDER [A] †	1/748 (0.13%)	0/480 (0%)
ARTERIAL STENOSIS [A] †	0/748 (0%)	2/480 (0.42%)
ARTERIAL STENOSIS LIMB [A] †	1/748 (0.13%)	2/480 (0.42%)
ARTERIAL THROMBOSIS LIMB [A] †	4/748 (0.53%)	0/480 (0%)
ARTERIOSCLEROSIS [A] †	1/748 (0.13%)	1/480 (0.21%)
ARTERIOSCLEROSIS OBLITERANS [A] †	2/748 (0.27%)	0/480 (0%)
BRACHIOCEPHALIC VEIN STENOSIS [A] †	1/748 (0.13%)	0/480 (0%)
CIRCULATORY COLLAPSE [A] †	2/748 (0.27%)	0/480 (0%)
DEEP VEIN THROMBOSIS [A] †	5/748 (0.67%)	2/480 (0.42%)
DIABETIC VASCULAR DISORDER [A] †	4/748 (0.53%)	2/480 (0.42%)
EXTREMITY NECROSIS [A] †	2/748 (0.27%)	0/480 (0%)
FEMORAL ARTERIAL STENOSIS [A] †	3/748 (0.4%)	1/480 (0.21%)
FEMORAL ARTERY EMBOLISM [A] †	0/748 (0%)	1/480 (0.21%)
FEMORAL ARTERY OCCLUSION [A] †	2/748 (0.27%)	0/480 (0%)
HAEMATOMA [A] †	0/748 (0%)	1/480 (0.21%)
HYPERTENSION [A] †	9/748 (1.2%)	6/480 (1.25%)
HYPERTENSIVE CRISIS [A] †	2/748 (0.27%)	3/480 (0.63%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
HYPERTENSIVE EMERGENCY [A] †	2/748 (0.27%)	1/480 (0.21%)
HYPOTENSION [A] †	12/748 (1.6%)	6/480 (1.25%)
HYPOVOLAEMIC SHOCK [A] †	0/748 (0%)	1/480 (0.21%)
ILIAC ARTERY STENOSIS [A] †	1/748 (0.13%)	1/480 (0.21%)
INTERMITTENT CLAUDICATION [A] †	0/748 (0%)	2/480 (0.42%)
ISCHAEMIA [A] †	0/748 (0%)	1/480 (0.21%)
JUGULAR VEIN THROMBOSIS [A] †	0/748 (0%)	1/480 (0.21%)
MICROANGIOPATHY [A] †	0/748 (0%)	1/480 (0.21%)
ORTHOSTATIC HYPOTENSION [A] †	2/748 (0.27%)	1/480 (0.21%)
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE [A] †	4/748 (0.53%)	2/480 (0.42%)
PERIPHERAL ARTERY ANEURYSM [A] †	1/748 (0.13%)	0/480 (0%)
PERIPHERAL ISCHAEMIA [A] †	7/748 (0.94%)	6/480 (1.25%)
PERIPHERAL VASCULAR DISORDER [A] †	4/748 (0.53%)	3/480 (0.63%)
PHLEBITIS [A] †	1/748 (0.13%)	0/480 (0%)
STEAL SYNDROME [A] †	1/748 (0.13%)	1/480 (0.21%)
SUBCLAVIAN VEIN THROMBOSIS [A] †	1/748 (0.13%)	0/480 (0%)
VASCULAR CALCIFICATION [A] †	1/748 (0.13%)	0/480 (0%)
VASCULAR RUPTURE [A] †	1/748 (0.13%)	0/480 (0%)
VASCULAR STENOSIS [A] †	0/748 (0%)	1/480 (0.21%)
VASCULITIS [A] †	1/748 (0.13%)	0/480 (0%)
VENA CAVA THROMBOSIS [A] †	1/748 (0.13%)	0/480 (0%)

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
VENOUS INSUFFICIENCY [A] †	1/748 (0.13%)	0/480 (0%)
VENOUS STENOSIS [A] †	1/748 (0.13%)	2/480 (0.42%)
VENOUS THROMBOSIS [A] †	1/748 (0.13%)	0/480 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
Total	624/748 (83.42%)	390/480 (81.25%)
Blood and lymphatic system disorders		
ANAEMIA [A] †	41/748 (5.48%)	25/480 (5.21%)
Cardiac disorders		
ATRIAL FIBRILLATION [A] †	42/748 (5.61%)	30/480 (6.25%)
Endocrine disorders		
HYPERPARATHYROIDISM SECONDARY [A] †	57/748 (7.62%)	44/480 (9.17%)
Gastrointestinal disorders		
ABDOMINAL PAIN [A] †	46/748 (6.15%)	22/480 (4.58%)
ABDOMINAL PAIN UPPER [A] †	37/748 (4.95%)	27/480 (5.62%)
CONSTIPATION [A] †	52/748 (6.95%)	41/480 (8.54%)
DIARRHOEA [A] †	141/748 (18.85%)	96/480 (20%)
NAUSEA [A] †	59/748 (7.89%)	41/480 (8.54%)
VOMITING [A] †	73/748 (9.76%)	44/480 (9.17%)
General disorders		

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
PYREXIA [A] †	52/748 (6.95%)	27/480 (5.62%)
Infections and infestations		
BRONCHITIS [A] †	75/748 (10.03%)	49/480 (10.21%)
GASTROENTERITIS [A] †	33/748 (4.41%)	27/480 (5.62%)
INFLUENZA [A] †	48/748 (6.42%)	23/480 (4.79%)
NASOPHARYNGITIS [A] †	107/748 (14.3%)	64/480 (13.33%)
UPPER RESPIRATORY TRACT INFECTION [A] †	81/748 (10.83%)	63/480 (13.12%)
URINARY TRACT INFECTION [A] †	77/748 (10.29%)	57/480 (11.87%)
Injury, poisoning and procedural complications		
ARTERIOVENOUS FISTULA SITE COMPLICATION [A] †	83/748 (11.1%)	36/480 (7.5%)
ARTERIOVENOUS FISTULA THROMBOSIS [A] †	56/748 (7.49%)	24/480 (5%)
ARTERIOVENOUS GRAFT THROMBOSIS [A] †	53/748 (7.09%)	26/480 (5.42%)
CONTUSION [A] †	34/748 (4.55%)	27/480 (5.62%)
PROCEDURAL HYPOTENSION [A] †	97/748 (12.97%)	56/480 (11.67%)
VASCULAR GRAFT COMPLICATION [A] †	39/748 (5.21%)	22/480 (4.58%)
Metabolism and nutrition disorders		
FLUID OVERLOAD [A] †	83/748 (11.1%)	38/480 (7.92%)
HYPERKALAEMIA [A] †	47/748 (6.28%)	37/480 (7.71%)
HYPERPHOSPHATAEMIA [A] †	47/748 (6.28%)	22/480 (4.58%)
Musculoskeletal and connective tissue disorders		

	Methoxy Polyethylene Glycol-Epoetin Beta	Comparator ESA
	Affected/At Risk (%)	Affected/At Risk (%)
ARTHRALGIA [A] †	65/748 (8.69%)	42/480 (8.75%)
BACK PAIN [A] †	74/748 (9.89%)	44/480 (9.17%)
MUSCLE SPASMS [A] †	75/748 (10.03%)	56/480 (11.67%)
MUSCULOSKELETAL PAIN [A] †	55/748 (7.35%)	30/480 (6.25%)
OSTEOARTHRITIS [A] †	44/748 (5.88%)	24/480 (5%)
PAIN IN EXTREMITY [A] †	76/748 (10.16%)	41/480 (8.54%)
Nervous system disorders		
HEADACHE [A] †	83/748 (11.1%)	43/480 (8.96%)
Psychiatric disorders		
DEPRESSION [A] †	38/748 (5.08%)	21/480 (4.37%)
INSOMNIA [A] †	39/748 (5.21%)	33/480 (6.88%)
Renal and urinary disorders		
RENAL FAILURE CHRONIC [A] †	22/748 (2.94%)	28/480 (5.83%)
Respiratory, thoracic and mediastinal disorders		
COUGH [A] †	79/748 (10.56%)	58/480 (12.08%)
DYSPNOEA [A] †	62/748 (8.29%)	41/480 (8.54%)
Skin and subcutaneous tissue disorders		
PRURITUS [A] †	59/748 (7.89%)	35/480 (7.29%)
Vascular disorders		
HYPERTENSION [A] †	167/748 (22.33%)	109/480 (22.71%)
HYPOTENSION [A] †	31/748 (4.14%)	26/480 (5.42%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights

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