Trial record **1 of 2** for: NCT00542386
Previous Study | Return to List | Next Study

# A Study of MCI-196 in Chronic Kidney Disease Subjects on Dialysis With Hyperphosphatemia and Dyslipidaemia

**This study has been completed.**

**Sponsor:**
Mitsubishi Tanabe Pharma Corporation

**Information provided by (Responsible Party):**
Mitsubishi Tanabe Pharma Corporation

**ClinicalTrials.gov Identifier:**
NCT00542386

First received: October 10, 2007
Last updated: September 30, 2014
Last verified: September 2014
History of Changes

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

Results First Received: April 10, 2014

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Parallel Assignment;<br>Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor);<br>Primary Purpose: Treatment |
| **Conditions:** | Chronic Kidney Disease<br>Dialysis<br>Hyperphosphatemia<br>Dyslipidemia |
| **Interventions:** | Drug: MCI-196<br>Drug: Placebo |

## 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** |
|---|
| No text entered. |

### Pre-Assignment Details

| **Significant events and approaches for the overall study following participant enrollment, but prior to group assignment** |
|---|
| No text entered. |

### Reporting Groups

| | **Description** |
|---|---|
| **MCI-196: 3 g** | MCI-196: 3 g/ day |
| **MCI-196: 6 g** | MCI-196: 6 g/ day |
| **MCI-196: 9 g** | MCI-196: 9 g/ day |

| | |
|---|---|
| **MCI-196: 12 g** | MCI-196: 12 g/ day |
| **MCI-196: 15 g** | MCI-196: 15 g/ day |
| **Pooled Placebo** | Placebo 9 tablets, 12 tablets and 15 tablets/ day |

**Participant Flow: Overall Study**

| | MCI-196: 3 g | MCI-196: 6 g | MCI-196: 9 g | MCI-196: 12 g | MCI-196: 15 g | Pooled Placebo |
|---|---|---|---|---|---|---|
| **STARTED** | 104 | 102 | 99 | 103 | 102 | 132 |
| **COMPLETED** | 61 | 74 | 66 | 65 | 62 | 82 |
| **NOT COMPLETED** | 43 | 28 | 33 | 38 | 40 | 50 |
| **Adverse Event** | 1 | 7 | 7 | 8 | 13 | 4 |
| **Death** | 0 | 0 | 1 | 2 | 1 | 2 |
| **Lack of Efficacy** | 32 | 12 | 10 | 13 | 7 | 31 |
| **Physician Decision** | 1 | 0 | 0 | 1 | 0 | 0 |
| **Protocol Violation** | 0 | 0 | 1 | 0 | 0 | 4 |
| **Withdrawal by Subject** | 5 | 8 | 10 | 11 | 15 | 7 |
| **Other Reasons** | 4 | 1 | 4 | 3 | 4 | 2 |

## 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.** |
| Each one subject in the MCI-196 9 g group, MCI-196 12 g group, and MCI-196 15 g group were randomised but did not receive any study medication. Therefore these 3 subjects were excluded in the baseline characteristics analysis population. |

**Reporting Groups**

| | Description |
|---|---|
| **MCI-196: 3 g** | MCI-196: 3 g/ day |
| **MCI-196: 6 g** | MCI-196: 6 g/ day |
| **MCI-196: 9 g** | MCI-196: 9 g/ day |
| **MCI-196: 12 g** | MCI-196: 12 g/ day |
| **MCI-196: 15 g** | MCI-196: 15 g/ day |
| **Pooled Placebo** | Placebo 9 tablets, 12 tablets and 15 tablets/ day |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | MCI-196: 3 g | MCI-196: 6 g | MCI-196: 9 g | MCI-196: 12 g | MCI-196: 15 g | Pooled Placebo | Total |
|---|---|---|---|---|---|---|---|
| **Number of Participants [units: participants]** | 104 | 102 | 98 | 102 | 101 | 132 | 639 |
| **Age [units: years]** | 49.9 (12.20) | 48.7 (14.64) | 47.3 (12.55) | 49.5 (12.41) | 50.7 (11.34) | 48.5 (12.54) | 49.1 (12.65) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Mean (Standard Deviation)** | | | | | | | |
| **Gender [units: participants]** | | | | | | | |
| **Female** | **48** | **54** | **48** | **48** | **46** | **55** | **299** |
| **Male** | **56** | **48** | **50** | **54** | **55** | **77** | **340** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: The Change in Serum Phosphorus [ Time Frame: 12 weeks ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | The Change in Serum Phosphorus |
| **Measure Description** | The change from baseline to week 12 |
| **Time Frame** | 12 weeks |
| **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.** |
| ITT: The ITT population included all subjects who received a randomisation number, took study medication, and had at least 1 central laboratory serum phosphorus or LDL-C value after the start |

**Reporting Groups**

| | **Description** |
|---|---|
| **MCI-196: 3 g** | MCI-196: 3 g/ day |
| **MCI-196: 6 g** | MCI-196: 6 g/ day |
| **MCI-196: 9 g** | MCI-196: 9 g/ day |
| **MCI-196: 12 g** | MCI-196: 12 g/ day |
| **MCI-196: 15 g** | MCI-196: 15 g/ day |
| **Pooled Placebo** | Placebo 9 tablets, 12 tablets and 15 tablets/ day |

**Measured Values**

| | **MCI-196: 3 g** | **MCI-196: 6 g** | **MCI-196: 9 g** | **MCI-196: 12 g** | **MCI-196: 15 g** | **Pooled Placebo** |
|---|---|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **104** | **101** | **97** | **100** | **99** | **130** |
| **The Change in Serum Phosphorus [units: mg/dL] Mean (Standard Deviation)** | **-0.23 (1.62)** | **-0.77 (1.97)** | **-0.97 (1.68)** | **-0.71 (1.84)** | **-1.41 (1.43)** | **-0.12 (1.70)** |

**No statistical analysis provided for The Change in Serum Phosphorus**

2. Primary: The Change in LDL-cholesterol [ Time Frame: 12 weeks ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | The Change in LDL-cholesterol |
| **Measure Description** | The percentage change from baseline to week 12 |
| **Time Frame** | 12 weeks |
| **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.** |
|---|
| ITT: The ITT population included all subjects who received a randomisation number, took study medication, and had at least 1 central laboratory serum phosphorus or LDL-C value after the start of study medication. |

**Reporting Groups**

| | **Description** |
|---|---|
| **MCI-196: 3 g** | MCI-196: 3 g/ day |
| **MCI-196: 6 g** | MCI-196: 6 g/ day |
| **MCI-196: 9 g** | MCI-196: 9 g/ day |
| **MCI-196: 12 g** | MCI-196: 12 g/ day |
| **MCI-196: 15 g** | MCI-196: 15 g/ day |
| **Pooled Placebo** | Placebo 9 tablets, 12 tablets and 15 tablets/ day |

**Measured Values**

| | **MCI-196: 3 g** | **MCI-196: 6 g** | **MCI-196: 9 g** | **MCI-196: 12 g** | **MCI-196: 15 g** | **Pooled Placebo** |
|---|---|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **104** | **101** | **97** | **100** | **99** | **130** |
| **The Change in LDL-cholesterol [units: Percent change] Mean (Standard Deviation)** | **-16.66 (20.05)** | **-23.56 (20.99)** | **-27.64 (21.45)** | **-29.44 (25.28)** | **-27.46 (24.57)** | **2.77 (17.44)** |

**No statistical analysis provided for The Change in LDL-cholesterol**

3. Secondary: The Change in Total-cholesterol [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

4. Secondary: The Change in HDL-cholesterol [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

5. Secondary: The Change in Triglycerides [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

6. Secondary: The Change in PTH [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

7. Secondary: The Change in Ca [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

8. Secondary: The Change in Ca x P Ion Product [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

9. Secondary: The Incidence of Adverse Events [ Time Frame: 12 weeks ]

**Results not yet reported.** **Anticipated Reporting Date:** No text entered. **Safety Issue:** Yes

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | 12 weeks |
| **Additional Description** | Each one subject in the MCI-196 9 g group, MCI-196 12 g group, and MCI-196 15 g group were randomised but did not receive any study medication. Therefore these 3 subjects were excluded for the safety evaluation. |

**Reporting Groups**

| | Description |
|---|---|
| **MCI-196: 3 g** | MCI-196: 3 g/ day |
| **MCI-196: 6 g** | MCI-196: 6 g/ day |
| **MCI-196: 9 g** | MCI-196: 9 g/ day |
| **MCI-196: 12 g** | MCI-196: 12 g/ day |
| **MCI-196: 15 g** | MCI-196: 15 g/ day |
| **Pooled Placebo** | Placebo 9 tablets, 12 tablets and 15 tablets/ day |

**Serious Adverse Events**

| | MCI-196: 3 g | MCI-196: 6 g | MCI-196: 9 g | MCI-196: 12 g | MCI-196: 15 g | Pooled Placebo |
|---|---|---|---|---|---|---|
| **Total, serious adverse events** | | | | | | |
| **# participants affected / at risk** | **3/104 (2.88%)** | **1/102 (0.98%)** | **2/98 (2.04%)** | **7/102 (6.86%)** | **5/101 (4.95%)** | **8/132 (6.06%)** |
| **Cardiac disorders** | | | | | | |
| **Ischaemic cardiomyopathy** | | | | | | |
| **# participants affected / at risk** | **1/104 (0.96%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Cardiovascular insufficiency** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **1/101 (0.99%)** | **0/132 (0.00%)** |
| **Pericarditis** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Atrial fibrillation** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Eye disorders** | | | | | | |
| **Iritis** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Gastrointestinal disorders** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Ascites | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Nausea | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Vomiting | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Abdominal pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Retroperitoneal haematoma | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Haemorrhoids | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Gastrointestinal haemorrhage | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| General disorders | | | | | | |
| Mass | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Catheter site phlebitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Infections and infestations | | | | | | |
| Pyelonephritis chronic | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Cellulitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Upper respiratory tract infection | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Acute sinusitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Abscess limb | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Sepsis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Hepatitis B | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Injury, poisoning and procedural complications** | | | | | | |
| **Arteriovenous fistula thrombosis** | | | | | | |
| **# participants affected / at risk** | **1/104 (0.96%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Eye injury** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Shunt thrombosis** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Kidney rupture** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Road traffic accident** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Procedural hypotension** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Nervous system disorders** | | | | | | |
| **Haemorrhagic stroke** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **2/132 (1.52%)** |
| **Renal and urinary disorders** | | | | | | |
| **Azotaemia** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **1/98 (1.02%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Renal failure chronic** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | | | | |
| **Pulmonary oedema** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **1/98 (1.02%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Choking** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Surgical and medical procedures** | | | | | | |
| **Renal transplant** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Vascular disorders** | | | | | | |
| **Hypertension** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **1/98 (1.02%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | 12 weeks |
| **Additional Description** | Each one subject in the MCI-196 9 g group, MCI-196 12 g group, and MCI-196 15 g group were randomised but did not receive any study medication. Therefore these 3 subjects were excluded for the safety evaluation. |

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 0 |

**Reporting Groups**

| | Description |
|---|---|
| **MCI-196: 3 g** | MCI-196: 3 g/ day |
| **MCI-196: 6 g** | MCI-196: 6 g/ day |
| **MCI-196: 9 g** | MCI-196: 9 g/ day |
| **MCI-196: 12 g** | MCI-196: 12 g/ day |
| **MCI-196: 15 g** | MCI-196: 15 g/ day |
| **Pooled Placebo** | Placebo 9 tablets, 12 tablets and 15 tablets/ day |

**Other Adverse Events**

| | MCI-196: 3 g | MCI-196: 6 g | MCI-196: 9 g | MCI-196: 12 g | MCI-196: 15 g | Pooled Placebo |
|---|---|---|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | | | | |
| **# participants affected / at risk** | **47/104 (45.19%)** | **44/102 (43.14%)** | **49/98 (50.00%)** | **53/102 (51.96%)** | **59/101 (58.42%)** | **65/132 (49.24%)** |
| **Blood and lymphatic system disorders** | | | | | | |
| **Anaemia** | | | | | | |
| **# participants affected / at risk** | **1/104 (0.96%)** | **1/102 (0.98%)** | **0/98 (0.00%)** | **1/102 (0.98%)** | **2/101 (1.98%)** | **0/132 (0.00%)** |
| **Haemorrhagic disorder** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **1/101 (0.99%)** | **0/132 (0.00%)** |
| **Lymphadenopathy** | | | | | | |
| **# participants affected / at risk** | **0/104 (0.00%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **1/132 (0.76%)** |
| **Cardiac disorders** | | | | | | |
| **Congestive cardiomyopathy** | | | | | | |
| **# participants affected / at risk** | **1/104 (0.96%)** | **0/102 (0.00%)** | **0/98 (0.00%)** | **0/102 (0.00%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Myocardial ischaemia** | | | | | | |
| **# participants affected / at risk** | **1/104 (0.96%)** | **0/102 (0.00%)** | **1/98 (1.02%)** | **1/102 (0.98%)** | **0/101 (0.00%)** | **0/132 (0.00%)** |
| **Ventricular extrasystoles** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Supraventricular extrasystoles | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Aortic valve calcification | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Angina pectoris | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 2/102 (1.96%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Tachycardia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Extrasystoles | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Palpitations | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 2/102 (1.96%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Conduction disorder | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Bradycardia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 2/132 (1.52%) |
| Atrioventricular block first degree | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Bundle branch block left | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 2/132 (1.52%) |
| Arrhythmia supraventricular | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Ear and labyrinth disorders | | | | | | |
| Vertigo | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 1/102 (0.98%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Cerumen impaction | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Endocrine disorders | | | | | | |
| Hyperparathyroidism | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Hyperparathyroidism secondary | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 1/101 (0.99%) | 1/132 (0.76%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Parathyroid disorder | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Hyperthyroidism | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Eye disorders | | | | | | |
| Conjunctivitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Visual acuity reduced | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Eye haemorrhage | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Ocular hyperaemia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Myopia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Gastrointestinal disorders | | | | | | |
| Toothache | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Diarrhoea | | | | | | |
| # participants affected / at risk | 5/104 (4.81%) | 5/102 (4.90%) | 6/98 (6.12%) | 4/102 (3.92%) | 5/101 (4.95%) | 7/132 (5.30%) |
| Nausea | | | | | | |
| # participants affected / at risk | 4/104 (3.85%) | 9/102 (8.82%) | 12/98 (12.24%) | 19/102 (18.63%) | 20/101 (19.80%) | 0/132 (0.00%) |
| Hyperchlorhydria | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Flatulence | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 1/98 (1.02%) | 3/102 (2.94%) | 1/101 (0.99%) | 3/132 (2.27%) |
| Abdominal pain | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 2/102 (1.96%) | 4/98 (4.08%) | 1/102 (0.98%) | 3/101 (2.97%) | 1/132 (0.76%) |
| Frequent bowel movements | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Abdominal pain upper | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 3/102 (2.94%) | 0/98 (0.00%) | 3/102 (2.94%) | 6/101 (5.94%) | 2/132 (1.52%) |
| Dyspepsia | | | | | | |
| # participants affected / at risk | 4/104 (3.85%) | 8/102 (7.84%) | 7/98 (7.14%) | 5/102 (4.90%) | 9/101 (8.91%) | 1/132 (0.76%) |
| Proctalgia | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Constipation | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 1/102 (0.98%) | 6/98 (6.12%) | 0/102 (0.00%) | 5/101 (4.95%) | 2/132 (1.52%) |
| Eructation | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Epigastric discomfort | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 1/102 (0.98%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Irritable bowel syndrome | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Vomiting | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 4/102 (3.92%) | 8/98 (8.16%) | 11/102 (10.78%) | 6/101 (5.94%) | 2/132 (1.52%) |
| Abdominal discomfort | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 2/102 (1.96%) | 1/98 (1.02%) | 1/102 (0.98%) | 3/101 (2.97%) | 2/132 (1.52%) |
| Dry mouth | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 2/98 (2.04%) | 1/102 (0.98%) | 2/101 (1.98%) | 4/132 (3.03%) |
| Odynophagia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Abnormal faeces | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Dyschezia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Faecaloma | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 2/102 (1.96%) | 0/101 (0.00%) | 2/132 (1.52%) |
| Faeces discoloured | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Infrequent bowel movements | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Retching | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Gastritis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 2/132 (1.52%) |
| Abdominal distension | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 3/102 (2.94%) | 2/98 (2.04%) | 7/102 (6.86%) | 6/101 (5.94%) | 4/132 (3.03%) |
| Gastritis erosive | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 3/101 (2.97%) | 0/132 (0.00%) |
| Painful defaecation | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Peritonitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Gastrointestinal hypermotility | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Defaecation urgency | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Faeces pale | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Haemorrhoidal haemorrhage | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Haemorrhoids | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 2/102 (1.96%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Diarrhoea haemorrhagic | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Gastric disorder | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Dysphagia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Gastrointestinal pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Gastric ulcer | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Abdominal rigidity | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Duodenal ulcer | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Erosive oesophagitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Tongue disorder | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Duodenitis | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Gastrointestinal sounds abnormal | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Gastrointestinal motility disorder | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| General disorders | | | | | | |
| Asthenia | | | | | | |
| # participants affected / at risk | 4/104 (3.85%) | 1/102 (0.98%) | 3/98 (3.06%) | 3/102 (2.94%) | 4/101 (3.96%) | 1/132 (0.76%) |
| Pyrexia | | | | | | |
| # participants affected / at risk | 4/104 (3.85%) | 1/102 (0.98%) | 1/98 (1.02%) | 0/102 (0.00%) | 1/101 (0.99%) | 1/132 (0.76%) |
| Chills | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Chest discomfort | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 2/98 (2.04%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Malaise | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 2/102 (1.96%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Oedema peripheral | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 1/102 (0.98%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Thirst | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Fatigue | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Catheter related complication | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Non-cardiac chest pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Hepatobiliary disorders | | | | | | |
| Hepatic cirrhosis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Hepatitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Cholelithiasis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Hepatitis toxic | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Biliary colic | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Immune system disorders | | | | | | |
| Hypersensitivity | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Drug hypersensitivity | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Kidney transplant rejection | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Infections and infestations | | | | | | |
| Breast abscess | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Injection site abscess | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Urinary tract infection | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Upper respiratory tract infection | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 1/101 (0.99%) | 1/132 (0.76%) |
| Bacterial infection | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Varicella | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Gastroenteritis | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Laryngitis | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Nasopharyngitis | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Cystitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Cellulitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Bronchitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 2/132 (1.52%) |
| Vaginitis bacterial | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Cervicitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Salpingo-oophoritis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Influenza | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 2/98 (2.04%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Pharyngitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Sinusitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Respiratory tract infection | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 1/102 (0.98%) | 2/101 (1.98%) | 2/132 (1.52%) |
| Helicobacter infection | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Herpes zoster | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Pulmonary tuberculosis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Respiratory tract infection viral | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 3/132 (2.27%) |
| Oesophageal candidiasis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Hepatitis C | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Viral infection | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Injury, poisoning and procedural complications | | | | | | |
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Haemodialysis-induced symptom | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 2/102 (1.96%) | 0/98 (0.00%) | 1/102 (0.98%) | 2/101 (1.98%) | 2/132 (1.52%) |
| Procedural hypotension | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 2/132 (1.52%) |
| Contusion | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Traumatic haematoma | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Procedural hypertension | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 3/98 (3.06%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Extensive interdialytic weight gain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Operative haemorrhage | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Arteriovenous fistula thrombosis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Fall | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Ear injury | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Arteriovenous fistula site complication | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Thermal burn | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Investigations | | | | | | |
| Blood parathyroid hormone increased | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 1/102 (0.98%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 3/132 (2.27%) |
| Blood pressure increased | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 1/102 (0.98%) | 0/98 (0.00%) | 2/102 (1.96%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Weight increased | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Weight decreased | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 2/101 (1.98%) | 1/132 (0.76%) |
| Blood phosphorus increased | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 0/102 (0.00%) | 1/98 (1.02%) | 1/102 (0.98%) | 0/101 (0.00%) | 3/132 (2.27%) |
| Cardiac murmur | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Body temperature increased | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Aspartate aminotransferase increased | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Blood creatine phosphokinase increased | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Gamma-glutamyltransferase increased | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Carotid bruit | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Blood alkaline phosphatase increased | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 2/98 (2.04%) | 1/102 (0.98%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Blood pressure decreased | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Heart rate increased | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| ECG signs of myocardial ischaemia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Blood calcium decreased | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Blood phosphorus decreased | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Metabolism and nutrition disorders | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Hyperphosphataemia | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Decreased appetite | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 1/102 (0.98%) | 1/98 (1.02%) | 6/102 (5.88%) | 4/101 (3.96%) | 1/132 (0.76%) |
| Cachexia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Polydipsia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Hyperkalaemia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 3/132 (2.27%) |
| Hypocalcaemia | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 2/102 (1.96%) | 3/98 (3.06%) | 6/102 (5.88%) | 2/101 (1.98%) | 3/132 (2.27%) |
| Fluid retention | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 1/132 (0.76%) |
| Hyperlipidaemia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Abnormal weight gain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Appetite disorder | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Increased appetite | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Musculoskeletal and connective tissue disorders | | | | | | |
| Arthritis | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Neck pain | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Pain in extremity | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 2/102 (1.96%) | 1/101 (0.99%) | 2/132 (1.52%) |
| Muscle spasms | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 1/101 (0.99%) | 2/132 (1.52%) |
| Arthralgia | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 2/98 (2.04%) | 1/102 (0.98%) | 1/101 (0.99%) | 5/132 (3.79%) |
| Bone pain | | | | | | |
| | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | | | | | | |
| Pain in jaw | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Back pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Musculoskeletal pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Myalgia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Arthropathy | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Osteochondrosis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | |
| Fibroadenoma of breast | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Nervous system disorders | | | | | | |
| Headache | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 1/102 (0.98%) | 2/98 (2.04%) | 4/102 (3.92%) | 0/101 (0.00%) | 4/132 (3.03%) |
| Hypertonia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Hypotonia | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Intercostal neuralgia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Tremor | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Uraemic neuropathy | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Paraesthesia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Convulsions local | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Encephalopathy | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Dizziness | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 2/101 (1.98%) | 1/132 (0.76%) |
| Dysgeusia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Somnolence | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Parosmia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Tonic convulsion | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Polyneuropathy | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Trigeminal neuralgia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Psychiatric disorders | | | | | | |
| Sleep disorder | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Insomnia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 1/98 (1.02%) | 1/102 (0.98%) | 1/101 (0.99%) | 2/132 (1.52%) |
| Anxiety | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 2/98 (2.04%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Hallucination, auditory | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Decreased activity | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Emotional distress | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Reproductive system and breast disorders | | | | | | |
| Menorrhagia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 2/102 (1.96%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Oligomenorrhoea | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Breast pain | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Respiratory, thoracic and mediastinal disorders | | | | | | |
| Dyspnoea | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Epistaxis | | | | | | |
| # participants affected / at risk | 2/104 (1.92%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 4/132 (3.03%) |
| Cough | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 2/98 (2.04%) | 1/102 (0.98%) | 1/101 (0.99%) | 1/132 (0.76%) |
| Throat irritation | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Asthma | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Rhinitis allergic | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Oropharyngeal pain | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 2/102 (1.96%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Nasal dryness | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Skin and subcutaneous tissue disorders | | | | | | |
| Rash pruritic | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Pruritus | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 1/102 (0.98%) | 2/98 (2.04%) | 3/102 (2.94%) | 1/101 (0.99%) | 4/132 (3.03%) |
| Alopecia | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 2/98 (2.04%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Cutaneous vasculitis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 1/98 (1.02%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Rash papular | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Dermatitis allergic | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Erythema | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 1/132 (0.76%) |
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Cutaneous lupus erythematosus | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Dry skin | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 1/132 (0.76%) |
| Surgical and medical procedures | | | | | | |
| Renal transplant | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 1/98 (1.02%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Nephrectomy | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Vascular disorders | | | | | | |
| Hypertensive crisis | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Hypotension | | | | | | |
| # participants affected / at risk | 1/104 (0.96%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |
| Hypertension | | | | | | |
| # participants affected / at risk | 3/104 (2.88%) | 6/102 (5.88%) | 6/98 (6.12%) | 2/102 (1.96%) | 5/101 (4.95%) | 4/132 (3.03%) |
| Aortic stenosis | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 1/102 (0.98%) | 0/98 (0.00%) | 0/102 (0.00%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Haematoma | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 3/102 (2.94%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Blood pressure fluctuation | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 1/102 (0.98%) | 0/101 (0.00%) | 0/132 (0.00%) |
| Arteriosclerosis obliterans | | | | | | |
| # participants affected / at risk | 0/104 (0.00%) | 0/102 (0.00%) | 0/98 (0.00%) | 0/102 (0.00%) | 1/101 (0.99%) | 0/132 (0.00%) |

## 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:**

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| 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:<br>☐ 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.<br>☐ 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.<br>☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.<br>**Restriction Description:** No text entered. |

**Results Point of Contact:**

Name/Title: Clinical Trials, Information Desk
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|---|---|
| Responsible Party: | Mitsubishi Tanabe Pharma Corporation |
| ClinicalTrials.gov Identifier: | NCT00542386 History of Changes |
| Other Study ID Numbers: | MCI-196-E08 |
| Study First Received: | October 10, 2007 |
| Results First Received: | April 10, 2014 |
| Last Updated: | September 30, 2014 |
| Health Authority: | United States: Food and Drug Administration<br>Italy: Ethics Committee<br>Russia: Ministry of Health of the Russian Federation<br>Macedonia: Ministry of Health<br>Serbia and Montenegro: Agency for Drugs and Medicinal Devices<br>Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products<br>Ukraine: State Pharmacological Center - Ministry of Health<br>Hungary: National Institute of Pharmacy<br>Malaysia: Ministry of Health |