**Supplementary Table 3.** Adverse drug reactions (by system organ class)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Safety analysis set (n=3,231)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of AE</td>
<td>606</td>
</tr>
<tr>
<td>Patients with an AE</td>
<td>450 (13.93)</td>
</tr>
<tr>
<td>Total number of ADR</td>
<td>193</td>
</tr>
<tr>
<td>Patients with an ADR</td>
<td>166 (5.14)</td>
</tr>
</tbody>
</table>

Type of ADR

- **Gastrointestinal disorders**: 22 (0.68)
- **Infections and infestations**: 17 (0.53)
- **Nervous system disorders**: 14 (0.43)
- **General disorders and administration site conditions**: 10 (0.31)
- **Investigations**: 21 (0.65)\(^{a}\)
  - **Weight decreased**: 17 (0.53)
- **Renal and urinary disorders**: 28 (0.87)
- **Pollakiuria**: 19 (0.59)
- **Reproductive system and breast disorders**: 32 (0.99)
- **Vulvovaginal pruritus**: 18 (0.56)
- **Pruritus genital**: 9 (0.28)
- **Metabolism and nutrition disorders**: 8 (0.25)
- **Hypoglycemia**: 3 (0.09)
- **Skin and subcutaneous tissue disorders**: 19 (0.59)
- **Pruritus**: 15 (0.46)
- **Musculoskeletal and connective tissue disorders**: 4 (0.12)
- **Respiratory, thoracic, and mediastinal disorders**: 3 (0.09)
- **Injury, poisoning, and procedural complications**: 3 (0.09)
- **Vascular disorders**: 1 (0.03)
- **Psychiatric disorders**: 1 (0.03)
- **Ear and labyrinth disorders**: 2 (0.06)
- **Blood and lymphatic system disorders**: 2 (0.06)

Values are presented as number (%).
AE, adverse event; ADR, adverse drug reaction.

\(^{a}\)Classified by system organ class (MedDRA version 20.0).

\(^{b}\)Composed of 17 subjects with weight decrease, 1 subject with weight increase, 1 subject with abnormal electrocardiogram, 1 subject with hemoglobin decreased, and 1 subject with urine output increased.