Revision of PRECAUTIONS

Apixaban
Edoxaban tosilate hydrate
Dabigatran etexilate methanesulfonate
Rivaroxaban

November 21, 2023

Therapeutic category
Anticoagulants

Non-proprietary name
Apixaban
Edoxaban tosilate hydrate
Dabigatran etexilate methanesulfonate
Rivaroxaban
Safety measure
PRECAUTIONS should be revised.
**Revised language is underlined.**

<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. ADVERSE REACTIONS</td>
<td>11. ADVERSE REACTIONS</td>
</tr>
<tr>
<td>11.1 Clinically Significant Adverse Reactions</td>
<td>11.1 Clinically Significant Adverse Reactions</td>
</tr>
<tr>
<td>(N/A)</td>
<td><strong>Acute kidney injury</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Acute kidney injury may occur after administration of oral anticoagulants. Among cases of acute kidney injury after administration of oral anticoagulants, cases in which haematuria was noted or a renal biopsy showed numerous red cell casts in the renal tubules have been reported.</strong></td>
</tr>
</tbody>
</table>


(N/A) Not Applicable. No corresponding language is included in the current PRECAUTIONS.