**Summary for ARTG Entry:** 101436 PANADEINE EXTRA tablet blister pack

**ARTG Entry for** Medicine Registered

**Sponsor** GlaxoSmithKline Consumer Healthcare Australia Pty Ltd

**Postal Address** Locked Bag 3, Ermington, NSW, 2115 Australia

**ARTG Start Date** 13/05/2004

**Product category** Medicine

**Status** Active

**Approval area** Drug Safety Evaluation Branch

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### Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

### Products

1. **PANADEINE EXTRA tablet blister pack**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Medicine Product</td>
<td>14/03/2018 12:07:08 PM</td>
</tr>
</tbody>
</table>

### Permitted Indications

No Permitted Indications included on Record

### Indication Requirements

No Indication Requirements included on Record

### Standard Indications

No Standard Indications included on Record

### Specific Indications

Temporary relief of moderate to severe acute pain associated with strong headaches, migraine headaches, dental surgery or toothache, menstrual pain and sports injuries (e.g. backaches and muscular pain).

### Warnings

See Product Information and Consumer Medicine Information for this product

### Additional Product information

### Container information

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Life Time</th>
<th>Temperature</th>
<th>Closure</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blister Pack</td>
<td>Not recorded</td>
<td>2 Years</td>
<td>Store below 30 degrees Celsius</td>
<td>Not recorded</td>
<td>Not recorded</td>
</tr>
</tbody>
</table>

### Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>24</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>6</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>12</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

### Components

1.

### Dosage Form

Tablet, uncoated

### Route of Administration

Oral

### Visual Identification

White to off-white capsule shaped tablets, marked PAN15 and scored on one side, with a plain reverse.

### Active Ingredients

- codeine phosphate hemihydrate 15 mg
- Paracetamol 500 mg
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