Public Summary

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

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>Single Medicine Product</th>
</tr>
</thead>
</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 (eg. 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 Table, 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