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

Product Type Single Medicine Product

Effective date 14/03/2018 12:07:08 PM

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

Type Blister Pack

Material Not recorded

Life Time 2 Years

Temperature Store below 30 degrees Celsius

Closure Not recorded

Conditions Not recorded

Pack Size/Poison information

Pack Size

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<th>Poison Schedule</th>
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<tr>
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<td>(S4) Prescription Only Medicine</td>
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<tr>
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<td>(S4) Prescription Only Medicine</td>
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<td>6</td>
<td>(S4) Prescription Only Medicine</td>
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<tr>
<td>12</td>
<td>(S4) Prescription Only Medicine</td>
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</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

Produced at 24.05.2019 at 06:43:08 AEST

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