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
Poison Schedule

40
(S4) Prescription Only Medicine

24
(S4) Prescription Only Medicine

6
(S4) Prescription Only Medicine

12
(S4) Prescription Only Medicine

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