



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 153959 CIRCADIN melatonin 2 mg prolonged release tablet blister pack

ARTG entry for Medicine Registered
Sponsor RAD Data Australia Pty Ltd
Postal Address PKF Melbourne Level 12 440 Collins Street, Melbourne, VIC, 3000
 Australia
ARTG Start Date 25/11/2009
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. CIRCADIN melatonin 2 mg prolonged release tablet blister pack

Product Type	Single Medicine Product	Effective date	10/06/2016
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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

Monotherapy for the short term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PVDC/Al	5 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size

30 tablets
 7 tablets
 21 tablets

Poison Schedule

(S4) Prescription Only Medicine
 (S4) Prescription Only Medicine
 (S4) Prescription Only Medicine

Components

1. melatonin prolonged release tablet blister pack

Dosage Form

Tablet, modified release

Route of Administration

Oral

Visual Identification

White to off-white, round, biconvex tablets

Active Ingredients

Melatonin **2 mg**

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