Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	290162 Bedtime Buddy
ARTG entry for	Medicine Listed
Sponsor	Seipel Group Pty Ltd
Postal Address	PO Box 3449, NEWMARKET, QLD, 4051 Australia
ARTG Start Date	14/06/2017
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Bedtime Buddy

Product Type Single Medicine Product **Effective Date** 17/01/2021

Permitted Indications

Help maintain/support healthy prostate function

Maintain/support healthy bladder function

Maintain/support bladder health

Decrease/reduce/relieve urinary incontinence associated with medically diagnosed overactive bladder

Decrease/reduce/relieve urinary urgency associated with medically diagnosed overactive bladder

Maintain/support kidney function

Relieve urinary frequency

Indication Requirements

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.

Product presentation must only refer to medically diagnosed overactive bladder.

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Product presentation must not imply or refer to kidney disease.

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions

Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Crateva magna stem bark Extract dry concentrate	**120 mg**
Equivalent: Crateva magna (Dry)	3 g
Equisetum arvense herb Extract dry concentrate	**150 mg**
Equivalent: Equisetum arvense (Dry)	1.5 g
Lindera strychnifolia root Extract dry concentrate	**150 mg**
Equivalent: Lindera strychnifolia (Dry)	1.5 g

Other Ingredients (Excipients)

hypromellose
Oryza sativa
silicon dioxide