Public Summary

Summary for ARTG Entry:	290167	Urox
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Urox

Product Type Single Medicine Product **Effective Date** 11/03/2020

Permitted Indications

Maintain/support healthy bladder function

Helps enhance/promote bladder health

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

Indication Requirements

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

Product presentation must only refer to medically diagnosed overactive bladder.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult a medical practitioner (or healthcare professional) (or words to that effect).

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	Child resistant closure	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