



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	380407	Urox
ARTG entry for	Medicine Listed	
Sponsor	Seipel Group Pty Ltd	
Postal Address	PO Box 3449, NEWMARKET, QLD, 4051 Australia	
ARTG Start Date	8/12/2021	
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 . Urox

Product Type	Single Medicine Product	Effective Date	4/04/2022
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Permitted Indications

- Helps enhance/promote collagen formation
- Maintain/support collagen formation
- Maintain/support collagen health
- Maintain/support connective tissue health
- Helps enhance/promote connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy muscle contraction function
- Helps enhance/promote healthy muscle function
- Maintain/support muscle function
- Helps enhance/improve/promote/increase muscle strength
- Maintain/support muscle strength
- Helps enhance/improve/promote/increase healthy muscle tone
- Maintain/support muscle tone
- Helps enhance/promote healthy nerve conduction/transmission/neurotransmission
- Maintain/support nerve conduction
- Maintain/support female healthy hormonal balance
- Maintain/support healthy reproductive hormones
- Help maintain/support healthy prostate function
- Helps enhance/promote prostate health
- Maintain/support prostate health
- Maintain/support skin health
- Helps enhance/improve skin internal structure
- Maintain/support skin elasticity
- Maintain/support skin integrity/structure
- Helps enhance/improve skin strength
- Enhance/improve/promote skin healing
- Enhance/improve/promote skin repair/healing

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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
 Helps reduce occurrence of medically diagnosed cystitis
 Helps decrease/reduce/relieve burning sensation/irritation upon urination associated with medically diagnosed cystitis
 Helps decrease/reduce/relieve symptoms of medically diagnosed cystitis
 Maintain/support urinary tract health
 Maintain/support urinary tract function

Indication Requirements

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
 Label statement: If symptoms persist or worsen talk to your medical practitioner.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to medically diagnosed cystitis.
 Product presentation must not imply or refer to hormone imbalances.
 Product presentation must only refer to medically diagnosed overactive bladder.
 Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 If symptoms persist consult a medical practitioner (or healthcare professional) (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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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)

calcium hydrogen phosphate dihydrate
 hypromellose
 magnesium stearate

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microcrystalline cellulose

silicon dioxide

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