



Australian Government
Department of Health
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

Public Summary



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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.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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 kidney disease.

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

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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