



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	353308	Prorox
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Seipel Group Pty Ltd	
<b>Postal Address</b>	PO Box 3449, NEWMARKET, QLD, 4051 Australia	
<b>ARTG Start Date</b>	19/01/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Prorox

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/10/2021
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#### Permitted Indications

Maintain/support connective tissue health  
Help maintain/support healthy prostate function in males  
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 only refer to medically diagnosed overactive bladder.  
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, talk to your health professional.  
Product presentation must not imply or refer to kidney disease.  
Label statement: If symptoms persist or worsen talk to your medical practitioner.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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

#### Additional Product information

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**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>colecalfiferol</b>	<b>12.5 microgram</b>
<b>Crateva magna stem bark Extract dry concentrate</b>	<b>120 mg</b>
Equivalent: Crateva magna (Dry)	3 g
<b>Equisetum arvense herb Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Equisetum arvense (Dry)	1.5 g
<b>Lindera strychnifolia root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Lindera strychnifolia (Dry)	1.5 g
<b>selenomethionine</b>	<b>134 microgram</b>
Equivalent: selenium	27.5 microgram
<b>Serenoa repens fruit flesh Extract dry concentrate</b>	<b>320 mg</b>
Equivalent: Serenoa repens (Dry)	3.2 g
<b>zinc citrate</b>	<b>17.2 mg</b>
Equivalent: zinc	5.5 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate  
hypromellose  
magnesium stearate  
maltodextrin  
silicon dioxide  
starch sodium octenyl succinate  
sucrose

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