Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	353308	Prorox
ARTG entry for	Medicine Listed	
Sponsor	Seipel Group Pty Ltd	
Postal Address	PO Box 3449, NEWMARKET, QLD, 4051 Australia	
ARTG Start Date	19/01/2021	
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 . Prorox

Product Type Single Medicine Product **Effective Date** 19/01/2021

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 not imply or refer to kidney disease.

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

Product presentation must only refer to medically diagnosed overactive bladder.

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

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

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).

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.

Additional Product information

Public Summary

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

colecalciferol	**12.5 microgram**
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
selenomethionine	**134 microgram**
Equivalent: selenium	27.5 microgram
Serenoa repens fruit flesh Extract dry concentrate	**320 mg**
Equivalent: Serenoa repens (Dry)	3.2 g
zinc citrate	**17.2 mg**
Equivalent: zinc	5.5 mg

Other Ingredients (Excipients)

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