



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	337124	PRETORIUS THROAT-CLEAR MENTHOL
ARTG entry for	Medicine Listed	
Sponsor	Key-Sun Laboratories Pty Ltd	
Postal Address	PO Box 1381, MONA VALE, NSW, 2103 Australia	
ARTG Start Date	27/05/2020	
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 . PRETORIUS THROAT-CLEAR MENTHOL

Product Type	Single Medicine Product	Effective Date	1/07/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support general health and wellbeing
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis
- Maintain/support wound healing

Indication Requirements

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not use while breastfeeding.

Use in children under 12 years is not recommended.

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].



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Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Lozenge

Route of Administration Oral

Visual Identification

Active Ingredients

Anise Oil	3 mg
ascorbic acid	50 mg
Echinacea purpurea herb Juice fresh	63 mg
Equivalent: Echinacea purpurea (Fresh)	126 mg
Eucalyptus Oil	2 mg
Fennel Oil	3 mg
menthol	3 mg
Nigella sativa seed Oil fixed	2 mg
Peppermint Oil	5 mg
Primula veris root and rhizome Extract liquid	1 mg
Equivalent: Primula veris (Dry)	1 mg
Thyme Oil	5.8 mg
zinc gluconate	18.1185 mg
Equivalent: zinc	2.6 mg

Other Ingredients (Excipients)

Acacia
acesulfame potassium
betadex
maltitol
purified water
vegetable oil
white beeswax

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