



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	149461	Pretorius Throat-Clear Honey & Lemon Flavour
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Key-Sun Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 1381, MONA VALE, NSW, 2103 Australia	
<b>ARTG Start Date</b>	29/01/2008	
<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 . Pretorius Throat-Clear Honey & Lemon Flavour

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	9/12/2020
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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  
Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain  
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 itchy throat  
Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis  
Maintain/support wound healing

#### Indication Requirements

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].  
Not suitable for infants under the age of twelve months (or words to that effect).  
Do not use while breastfeeding.  
Use in children under 12 years is not recommended.  
Do not use if pregnant or likely to become pregnant (or words to that effect)



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**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**

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	20 mg
Equivalent: zinc	2.6 mg

**Other Ingredients (Excipients)**

Acacia  
acesulfame potassium  
betadex  
dl-alpha-tocopherol  
ethanol  
Flavour  
Honey  
maltitol solution  
propylene glycol  
purified water  
sorbitol solution (70 per cent) (non-crystallising)  
vegetable oil  
white beeswax

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