



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

## Public Summary

<b>Summary for ARTG Entry:</b>	297382	Thompson's Manuka Sore Throat Spray
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	11/12/2017	
<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 . Thompson's Manuka Sore Throat Spray

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/06/2021
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### Permitted Indications

- Decrease/reduce bacteria in the mouth
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mouth/oral mucosa mild inflammation
- Decrease/reduce/relieve mouth/oral mucosa mild inflammation
- Traditionally used in Western herbal medicine to soothe/relieve mouth/oral irritation
- Traditionally used in Western herbal medicine to maintain/support oral mucous membrane health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild mouth ulcers
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to relieve dry unproductive cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild throat inflammation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild throat infection
- Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild tonsillitis

### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Product presentation must not imply or refer to serious infections.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Product presentation must only refer to mild mouth ulcers.
- Product presentation must only refer to mild tonsillitis.
- Product presentation must not imply or refer to recurrent or persistent mouth lesions.

### Standard Indications

No Standard Indications included on Record

### Specific Indications



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No Specific Indications included on Record

**Warnings**

Contains ethanol or contains alcohol.  
 Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).  
 Not suitable for infants under the age of twelve months (or words to that effect).  
 Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.  
 If symptoms persist consult your healthcare practitioner (or words to that effect).  
 Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).  
 Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Althaea officinalis root Extract liquid</b>	<b>400 microlitre/mL</b>
Equivalent: Althaea officinalis (Dry)	80 mg/mL
<b>Calendula officinalis flower Extract liquid</b>	<b>40 microlitre/mL</b>
Equivalent: Calendula officinalis (Dry)	20 mg/mL
<b>Clove Bud Oil</b>	<b>2.5 microlitre/mL</b>
<b>Commiphora myrrha stem bark oleoresin Extract liquid</b>	<b>10 microlitre/mL</b>
Equivalent: Commiphora myrrha (Dry)	2 mg/mL
<b>Echinacea angustifolia root Extract liquid</b>	<b>40 microlitre/mL</b>
Equivalent: Echinacea angustifolia (Dry)	20 mg/mL
<b>Honey</b>	<b>20 mg/mL</b>
<b>Salvia officinalis herb top Extract liquid</b>	<b>120 microlitre/mL</b>
Equivalent: Salvia officinalis (Dry)	60 mg/mL

**Other Ingredients (Excipients)**

ethanol  
 Lemongrass Oil  
 menthol  
 methyl hydroxybenzoate  
 potassium sorbate  
 propyl hydroxybenzoate  
 purified water

Public Summary

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