



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|--------------------------|
| Summary for ARTG Entry: | 288866 | Thompson's Garlic Perles |
| ARTG entry for | Medicine Listed | |
| Sponsor | Integria Healthcare Australia Pty Ltd | |
| Postal Address | PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia | |
| ARTG Start Date | 12/05/2017 | |
| 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 . Thompson's Garlic Perles

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 8/06/2022 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Traditionally used in Western herbal medicine to relieve feelings of general malaise/general debility
Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to antispasmodic/spasmodic
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
Linked indication - Relieve feelings of general malaise/general debility
Linked indication - Relieve runny/dripping nose
Linked indication - Decrease/reduce/relieve cough
Linked indication - Decrease/reduce/relieve sneezing
Traditionally used in Western herbal medicine to decrease/reduce excess mucous
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
Traditionally used in Western herbal medicine to decrease/reduce/relieve sneezing
Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
Traditionally used in Western herbal medicine to relieve runny/dripping nose

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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Respiratory tract infections must be qualified by 'mild'.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--------------------------------|-------------|
| Garlic Oil | 1 mg |
| Equivalent: Garlic Oil (Fresh) | 3 g |

Other Ingredients (Excipients)

Gelatin

glycerol

Peppermint Oil

purified water

Soya Oil

vanillin

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