



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|------------|
| Summary for ARTG Entry: | 227878 | SINUS PLEX |
| ARTG entry for | Medicine Listed | |
| Sponsor | The Pharmaceutical Plant Company Pty Ltd | |
| Postal Address | 3 Sigma Drive, Croydon South, VIC, 3136 Australia | |
| ARTG Start Date | 12/09/2014 | |
| 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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . SINUS PLEX

| Product Type | Single Medicine Product | Effective Date | 19/07/2019 |
|--------------|-------------------------|----------------|------------|
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Permitted Indications

- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration in children over 5 years of age
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation in children
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues in children
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of hayfever
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of hayfever in children
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies in children
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of allergic rhinitis in children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of allergic rhinitis
- Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion in children
- Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion
- 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 in children
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children

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Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children
 Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis in children
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis
 Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough
 Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough in children
 Traditionally used in Western herbal medicine to decrease/reduce/relieve cough in children
 Traditionally used in Western herbal medicine to decrease/reduce/relieve cough
 Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis in children
 Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

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.
 Respiratory tract infections must be qualified by 'mild'.
 Product presentation must only refer to mild bronchitis.
 Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If coughing persists consult your doctor (or a healthcare professional) (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 ethanol or contains alcohol.
 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).

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

| | |
|--|--------------------------|
| Allium sativum bulb Extract liquid | 40 microlitre/mL |
| Equivalent: Allium sativum (Fresh) | 20 mg/mL |
| Euphrasia officinalis herb Extract liquid | 200 microlitre/mL |
| Equivalent: Euphrasia officinalis (Dry) | 200 mg/mL |
| Glycyrrhiza glabra root Extract liquid | 250 microlitre/mL |
| Equivalent: Glycyrrhiza glabra (Dry) | 250 mg/mL |
| Sambucus nigra flower Extract liquid | 200 microlitre/mL |
| Equivalent: Sambucus nigra (Dry) | 200 mg/mL |
| Scutellaria baicalensis root Extract liquid | 100 microlitre/mL |
| Equivalent: Scutellaria baicalensis (Dry) | 100 mg/mL |

Other Ingredients (Excipients)

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glycerol

Mentha X piperita

Pimpinella anisum

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