



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	343296	SinuClear
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	11/09/2020	
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 . SinuClear

Product Type	Single Medicine Product	Effective Date	11/09/2020
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Permitted Indications

- Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-coldness
- Traditionally used in Chinese medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Chinese medicine to decrease/reduce/relieve post nasal drip
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of allergic rhinitis
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of allergic rhinitis
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decongestant/relieve nasal congestion
- Traditionally used in Chinese medicine to decongestant/relieve nasal congestion
- Traditionally used in Chinese medicine to unblock/clear nasal passages
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu
 - Linked indication - Decongestant/relieve nasal congestion
- Traditionally used in Chinese medicine to decrease/reduce excess mucous
- Traditionally used in Chinese medicine to decrease/reduce/relieve sneezing
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of sinusitis
 - Linked indication - Analgesic/Anodyne/relieve pain
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decongestant/relieve nasal congestion
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of sinusitis
 - Linked indication - Decongestant/relieve nasal congestion
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve nasal itching
- Traditionally used in Chinese 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.



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If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica dahurica root Extract dry concentrate	142.9 mg
Equivalent: Angelica dahurica (Dry)	1 g
Houttuynia cordata herb top Extract dry concentrate	150 mg
Equivalent: Houttuynia cordata (Dry)	1.5 g
Magnolia liliflora flower bud Extract dry concentrate	112.5 mg
Equivalent: Magnolia liliflora (Dry)	675 mg
Mentha haplocalyx herb top Extract dry concentrate	65 mg
Equivalent: Mentha haplocalyx (Dry)	325 mg
Xanthium sibiricum fruit Extract dry concentrate	125 mg
Equivalent: Xanthium sibiricum (Dry)	875 mg

Other Ingredients (Excipients)

- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- purified water

Public Summary

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