



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	408657	Sambucol Black Elderberry Cold & Flu Double Strength
ARTG entry for	Medicine Listed	
Sponsor	Pharmacare Laboratories Pty Ltd	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	9/05/2023	
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 . Sambucol Black Elderberry Cold & Flu Double Strength

Product Type	Single Medicine Product	Effective Date	9/05/2023
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Permitted Indications

- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Decrease/reduce/relieve common cold duration
- Helps decrease/reduce/relieve the severity of symptoms of common colds and flu
- Decrease/reduce/relieve symptoms of common colds and flu
- Decrease/reduce/relieve mild upper respiratory tract congestion
- Decrease/reduce/relieve cough
- Relieve symptoms of sore throat/pharyngitis

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- 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 chronic fatigue syndrome.
- Respiratory tract infections must be qualified by 'mild'.

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



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Sambucus nigra fruit Juice dry	217.32 mg
Equivalent: Sambucus nigra (Juice fresh)	7.606 g

Other Ingredients (Excipients)

acetic acid

citric acid

colloidal anhydrous silica

Gelatin

magnesium stearate

maltodextrin

microcrystalline cellulose

polysorbate 20

purified water

silicon dioxide

sucrose stearate

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