



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	210684	Children's Immune Care
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	7/06/2013	
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 . Children's Immune Care

Product Type	Single Medicine Product	Effective Date	14/01/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support general health and wellbeing in children
- Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Maintain/support immune system health in children
- Traditionally used in Western herbal medicine to maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness in children
- Maintain/support immune system to fight illness in children
- 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 mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Indication Requirements

- 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 immunological diseases.
- Label statement: If symptoms persist, talk to your health professional.
- Respiratory tract infections must be qualified by 'mild'.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Label statement: Not to be used in children under 5 years.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	60 mg
betacarotene	1 mg
calcium ascorbate	44.99 mg
Equivalent: ascorbic acid	40 mg
Citrus bioflavonoids extract	10 mg
colecalfiferol	.0062 mg
Echinacea purpurea root and rhizome Extract dry concentrate	33.3 mg
Equivalent: Echinacea purpurea (Dry)	200 mg
Malpighia glabra fruit Extract dry concentrate	7.5 mg
Equivalent: Malpighia glabra (Dry)	30 mg
zinc gluconate	13.9 mg
Equivalent: zinc	2 mg

Other Ingredients (Excipients)

- ascorbyl palmitate
- citric acid
- colloidal anhydrous silica
- dl-alpha-tocopherol
- Flavour
- hydrogenated soya oil
- hydrolysed gelatin
- hypromellose
- magnesium stearate
- maize starch
- microcrystalline cellulose
- povidone
- silicon dioxide
- sorbitol
- sucrose
- Sunflower Oil
- tartaric acid
- thaumatin
- xylitol

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