



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321874	Manuka Honey Cold & Flu
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	16/08/2019	
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 . Manuka Honey Cold & Flu

Product Type	Single Medicine Product	Effective Date	30/08/2024
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body in children
Helps reduce/decrease free radical damage to body cells in children
Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in children
Traditionally used in Homoeopathic medicine to relieve eye discomfort in children
Maintain/support healthy eye function in children
Maintain/support eye health in children
Traditionally used in Homoeopathic medicine to relieve itchy eyes in children
Traditionally used in Homoeopathic medicine to relieve eye redness in children
Traditionally used in Homoeopathic medicine to relieve eye soreness
Maintain/support healthy eyesight/vision in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve watery eyes/excessive lacrimation
Maintain/support healthy growth and development
Maintain/support body mucous membrane health in children
Maintain/support general health and wellbeing when sun exposure is inadequate
Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing in children
Maintain/support general health and wellbeing in children
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing in children
Maintain/support hair health in children
Aids/assists teeth development in children
Maintain/support healthy teeth in children
Maintain/support teeth mineralisation in children
Maintain/support teeth strength in children
Maintain/support nail health/strength/thickness in children
Maintain/support bone health in children
Aids/assists healthy bone development/growth/building in children
Maintain/support bone strength in children
Help maintain/support bone mineralisation in children



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Traditionally used in Western herbal medicine to maintain/support immune system health in children
Maintain/support immune system health in children
Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children
Maintain/support healthy immune system function in children
Maintain/support muscle function in children
Maintain/support healthy neuromuscular system/function in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle pain/ache/soreness in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle tiredness in children
Aid/assist/helps protein synthesis in the body in children
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in children
Maintain/support cognitive function/mental function in healthy children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild dizziness/vertigo in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms in children
Maintain/support nerve conduction in children
Maintain/support nervous system function in children
Traditionally used in Homoeopathic medicine to decrease/reduce excess chest phlegm in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve common cold duration in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common colds and flu in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common colds and flu in children
 Linked indication - Decongestant/relieve nasal congestion
 Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
 Linked indication - Decrease/reduce/relieve throat irritation
 Linked indication - Relieve runny/dripping nose
 Linked indication - Enhance/improve/promote/increase cough productivity
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Decrease/reduce excess mucous
 Linked indication - Decrease/reduce/relieve sneezing
 Linked indication - Decrease/reduce/relieve chills associated with common cold
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of head cold in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of head cold in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of common cold symptoms in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
 Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration
 Linked indication - Decongestant/relieve nasal congestion
 Linked indication - Expectorant/clear respiratory tract mucous
 Linked indication - Decrease/reduce/relieve cough
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common cold in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial cough in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis in children
Traditionally used in Homoeopathic medicine to relieve symptoms of sore throat/pharyngitis in children
Maintain/support skin health in children
Maintain/support skin integrity/structure in children
Maintain/support skin regeneration in children
Maintain/support wound healing in children

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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Respiratory tract infections must be qualified by 'mild'.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must only refer to mild vertigo.

Product presentation must only refer to mild bronchitis.

Product presentation must not imply or refer to chronic fatigue syndrome.

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 medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Contains homeopathic ingredients.

Not suitable for infants under the age of twelve months (or words to that effect).

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

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 cepa bulb (Homeopathic)	5 microlitre/mL
Anemone pulsatilla whole plant (Homeopathic)	5 microlitre/mL
betacarotene	.15 mg/mL
colecalfiferol	.0002 mg/mL
Echinacea purpurea herb top flowering Extract dry concentrate	6.675 mg/mL
Equivalent: Echinacea purpurea (Dry)	26.7 mg/mL
Euphrasia officinalis whole plant (Homeopathic)	5 microlitre/mL
Gelsemium sempervirens root and rhizome (Homeopathic)	5 microlitre/mL
Hedera helix leaf Extract dry concentrate	5 mg/mL
Equivalent: Hedera helix (Dry)	20 mg/mL
Honey	325 mg/mL
Honey	65 mg/mL
Mentha X piperita herb Extract dry concentrate	13.33 mg/mL
Equivalent: Mentha X piperita (Dry)	66.65 mg/mL
Sambucus nigra flower Extract dry concentrate	41.66 mg/mL
Equivalent: Sambucus nigra (Dry)	250 mg/mL
sodium chloride (Homeopathic)	5 microlitre/mL
zinc glycinate	.443 mg/mL
Equivalent: zinc	.125 mg/mL



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Other Ingredients (Excipients)

dl-alpha-tocopherol
ethanol
Flavour
glycerol
maize starch
maltodextrin
methyl hydroxybenzoate
modified food starch
propyl hydroxybenzoate
purified water
silicon dioxide
vegetable oil
xanthan gum

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary