



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299705	Ki Cold & Flu Day / Night Formula
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	16/02/2018	
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 . Ki Cold & Flu Day / Night Formula

Product Type	Composite Pack	Effective Date	27/05/2020
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Permitted Indications

Traditionally used in Chinese medicine to dispel/expel/disperse/clear external/exogenous wind

Maintain/support general health and wellbeing

Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of allergic rhinitis

Linked indication - Anti-inflammatory/relieve inflammation

Linked indication - Helps decrease/reduce/relieve facial tenderness associated with allergic rhinitis

Linked indication - Relieve runny/dripping nose

Maintain/support immune system health

Enhance/improve/promote immune defence/immunity

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms

Linked indication - Analgesic/Anodyne/relieve pain

Linked indication - Decrease/reduce headache duration

Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

Decrease/reduce/relieve common cold duration

Helps decrease/reduce/relieve the severity of symptoms of common colds and flu

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common colds and flu

Linked indication - Relieve eye redness

Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Linked indication - Decongestant/relieve nasal congestion

Linked indication - Decrease/reduce excess chest phlegm

Linked indication - Relieve runny/dripping nose

Linked indication - Decrease/reduce/relieve cough

Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Linked indication - Helps reduce occurrence of symptoms of headaches

Linked indication - Decrease/reduce/relieve disturbed/restless sleep

Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness



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Linked indication - Relieve feelings of general malaise/general debility
Linked indication - Decrease/reduce/relieve throat irritation
Linked indication - Decrease/reduce/relieve mild throat inflammation
Linked indication - Expectorant/clear respiratory tract mucous
Linked indication - Decrease/reduce/relieve cough
Linked indication - Relieve runny/dripping nose
Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis
Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Linked indication - Decrease/reduce/relieve mild throat inflammation

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.
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.
Label statement: Not to be used in children under 5 years.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.
Product presentation must not imply or refer to serious immunological diseases.
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).
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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Andrographis paniculata	100 mg
zinc amino acid chelate	30 mg
Equivalent: zinc	6 mg
Zingiber officinale rhizome Extract dry concentrate	150 mg
Equivalent: Zingiber officinale (Fresh)	1.5 g

Other Ingredients (Excipients)

calcium carbonate
calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
curcumin
hypromellose



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macrogol 400
magnesium stearate
microcrystalline cellulose

2 . Formulation 2

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Magnolia liliflora flower Extract dry concentrate	300 mg
Equivalent: Magnolia liliflora (Dry)	3 g
Melissa officinalis leaf Extract dry concentrate	150 mg
Equivalent: Melissa officinalis (Dry)	1.5 g
Mentha haplocalyx leaf Extract dry concentrate	300 mg
Equivalent: Mentha haplocalyx (Dry)	3 g
Zingiber officinale rhizome Extract dry concentrate	100 mg
Equivalent: Zingiber officinale (Fresh)	1 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose

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