



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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| 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 |
|---------------------|----------------|-----------------------|------------|

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 - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
- 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 - Relieve weariness/tiredness/fatigue/feeling of weakness
 - Linked indication - Relieve feelings of general malaise/general debility

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Linked indication - Decrease/reduce/relieve disturbed/restless sleep
 Linked indication - Decrease/reduce/relieve throat irritation
 Linked indication - Expectorant/clear respiratory tract mucous
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Relieve runny/dripping nose
 Linked indication - Decrease/reduce/relieve mild throat inflammation
 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

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 Label statement: If symptoms persist, talk to your health professional.
 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.
 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 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 chronic fatigue syndrome.
 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).
 If symptoms persist consult your healthcare practitioner (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).

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

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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