Public Summary

Summary for ARTG Entry:	232541 Ki Cold and (&) Flu Attack
ARTG entry for	Medicine Listed
Sponsor	Martin & Pleasance Pty Ltd
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	12/01/2015
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 . Ki Cold and (&) Flu Attack

Product Type Single Medicine Product **Effective Date** 22/01/2020

Permitted Indications

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

Maintain/support general health and wellbeing

Traditionally used in Western herbal 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

Enhance/improve/promote immune defence/immunity

Maintain/support healthy immune system function

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

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 - Decrease/reduce/relieve disturbed/restless sleep
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
Linked indication - Decrease/reduce/relieve throat irritation
Linked indication - Relieve feelings of general malaise/general debility
Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

Linked indication - Analgesic/Anodyne/relieve pain
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.

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 serious immunological diseases.

Label statement: Not to be used in children under 5 years.

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.

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

Respiratory tract infections must be qualified by 'mild'.

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.

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).

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
macrogol 400
magnesium stearate
microcrystalline cellulose

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