Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	237232	Ki Allergy & Hayfever Control Formula

ARTG entry for	Medicine Listed
Sponsor	Martin & Pleasance Pty Ltd
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	6/05/2015
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 Allergy & Hayfever Control Formula

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

Permitted Indications

Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Decrease/reduce/relieve symptoms of hayfever

Helps decrease/reduce/relieve symptoms of mild allergies
- Linked indication - Relieve runny/dripping nose
- Linked indication - Helps decrease/reduce/relieve nasal itching
- Linked indication - Decrease/reduce/relieve sneezing
- Linked indication - Antipruritic/Relieves itchy skin
- Linked indication - Relieve itchy eyes

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

Decrease/reduce/relieve symptoms of allergic rhinitis
- Linked indication - Helps decrease/reduce/relieve nasal itching
- Linked indication - Decrease/reduce/relieve sneezing
- Linked indication - Decongestant/relieve nasal congestion

Helps decrease/reduce/relieve symptoms of seasonal allergies

Maintain/support immune system health

Enhance/improve/promote immune defence/immunity

Helps enhance/improve/promote immune system function

Decrease/reduce/relieve headache symptoms

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

Traditionally used in Chinese medicine to decongestant/relieve nasal congestion

Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm

Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous

Indication Requirements

Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

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.

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

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

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: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, uncoated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Astragalus membranaceus root Extract dry concentrate	**106 mg**
Equivalent: Astragalus membranaceus (Dry)	2.12 g
Astragalus membranaceus	**160.08 mg**
Magnolia liliflora flower Extract dry concentrate	**150 mg**
Equivalent: Magnolia liliflora (Dry)	1.5 g
quercetin dihydrate	**200 mg**
Zingiber officinale rhizome Extract dry concentrate	**150 mg**
Equivalent: Zingiber officinale (Fresh)	1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
magnesium stearate
microcrystalline cellulose

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