



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338445	AllergE
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	26/06/2020	
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 . AllergE

Product Type	Single Medicine Product	Effective Date	26/06/2020
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Permitted Indications

- Traditionally used in Chinese medicine to soothe/descend Qi
- Traditionally used in Chinese medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of hayfever
 - Linked indication - Helps decrease/reduce/relieve nasal itching
 - Linked indication - Decongestant/relieve nasal congestion
 - Linked indication - Relieve eye redness
 - Linked indication - Relieve itchy eyes
 - Linked indication - Relieve runny/dripping nose
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of mild allergies
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of allergic rhinitis
 - Linked indication - Helps decrease/reduce/relieve nasal itching
 - Linked indication - Decongestant/relieve nasal congestion
 - Linked indication - Relieve eye redness
 - Linked indication - Relieve itchy eyes
 - Linked indication - Relieve runny/dripping nose
- Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis
- Traditionally used in Chinese medicine to soothe/relieve skin inflammation

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- 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.
- 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 only refer to mild eczema.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Individuals taking anticoagulants should seek medical advice before taking this product. AND Individuals at risk of bleeding problems should seek advice from their health practitioner prior to taking this product.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bupleurum falcatum root Extract dry concentrate	120 mg
Equivalent: Bupleurum falcatum (Dry)	1.8 g
Glycyrrhiza uralensis root and stolon Extract dry concentrate	90 mg
Equivalent: Glycyrrhiza uralensis (Dry)	450 mg
Panax ginseng root Extract dry concentrate	26.67 mg
Equivalent: Panax ginseng (Dry)	400 mg
Pinellia ternata rhizome Extract dry concentrate	100 mg
Equivalent: Pinellia ternata (Dry)	500 mg
Scutellaria baicalensis root Extract dry concentrate	250 mg
Equivalent: Scutellaria baicalensis (Dry)	2.5 g
Zingiber officinale rhizome Extract dry concentrate	25 mg
Equivalent: Zingiber officinale (Dry)	1.25 g
Ziziphus jujuba var. spinosa fruit Extract dry concentrate	50 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	200 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
 hypromellose
 magnesium stearate
 maltodextrin
 microcrystalline cellulose
 purified water

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