Public Summary

Summary for ARTG Entry:	335073	Viraforce
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	24/04/2020	
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 . Viraforce

Product Type Single Medicine Product **Effective Date** 24/04/2020

Permitted Indications

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Decrease/reduce/relieve symptoms of common colds and flu

- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Linked indication - Relieve runny/dripping nose
- Linked indication - Decrease/reduce/relieve cough
- Linked indication - Decrease/reduce/relieve disturbed/restless sleep

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

- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- Linked indication - Relieve runny/dripping nose
- Linked indication - Decrease/reduce/relieve cough
- Linked indication - Decrease/reduce/relieve disturbed/restless sleep

Relieve symptoms of sore throat/pharyngitis

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.

Respiratory tract infections must be qualified by 'mild'.

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (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	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Andrographis paniculata	**200 mg**
ascorbic acid	**250 mg**
Echinacea purpurea root Extract dry concentrate	**125 mg**
Equivalent: Echinacea purpurea (Dry)	750 mg
Lonicera japonica flower bud Extract dry concentrate	**100 mg**
Equivalent: Lonicera japonica (Dry)	1 g
Olea europaea leaf Extract dry concentrate	**125 mg**
Equivalent: Olea europaea (Dry)	1.25 g
zinc glycinate	**26.1 mg**
Equivalent: zinc	8 mg

Other Ingredients (Excipients)

calcium carbonate
colloidal anhydrous silica
croscarmellose sodium
disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
potable water
potassium acetate

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