



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	306994	Thompson's One-A-Day Echinacea 4000
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	13/07/2018	
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.

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 . Thompson's One-A-Day Echinacea 4000

Product Type	Single Medicine Product	Effective Date	2/09/2021
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Permitted Indications

- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Maintain/support immune system health
- Helps enhance/improve/promote immune system function
- Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
- Traditionally used in Western herbal medicine to maintain/support healthy immune system function
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Maintain/support immune system to fight illness
- Helps stimulate a healthy immune system response
- Traditionally used in Western herbal medicine to helps stimulate a healthy immune system response
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve cough
- Decrease/reduce/relieve sneezing
- Decrease/reduce/relieve the severity of common cold symptoms
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
- Decrease/reduce/relieve the severity of common cold symptoms
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Relieve symptoms of mild upper respiratory tract infections
- Helps reduce occurrence of symptoms of upper respiratory tract infections
- Decrease/reduce/relieve cough
- Relieve runny/dripping nose

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Relieve symptoms of sore throat/pharyngitis

Indication Requirements

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

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).

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).

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

Echinacea angustifolia root Extract dry concentrate	25 mg
Equivalent: Echinacea angustifolia (Dry)	100 mg
Echinacea purpurea root Extract dry concentrate	250 mg
Equivalent: Echinacea purpurea (Dry)	1.5 g
Echinacea purpurea herb top flowering Juice dry	53.34 mg
Equivalent: Echinacea purpurea (Fresh)	2.4 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
crospovidone
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose

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