



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	322405	BLACKMORES ECHINACEA ACE + ZINC
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Blackmores Ltd	
<b>Postal Address</b>	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
<b>ARTG Start Date</b>	28/08/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . BLACKMORES ECHINACEA ACE + ZINC

Product Type	Effective Date
Single Medicine Product	28/08/2019

### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support general health and wellbeing
- Traditionally used in Native American medicine to maintain/support immune system health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to helps reduce occurrence of common colds
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve the severity of common cold symptoms
- Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of upper respiratory tract infections

### Indication Requirements

- 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: If symptoms persist, talk to your health professional.

### Standard Indications

No Standard Indications included on Record

### Specific Indications



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No Specific Indications included on Record

#### Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).  
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
Adults only. OR Not to be used in children under two years of age without medical advice (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**                      Tablet, film coated  
**Route of Administration**        Oral

##### Visual Identification

#### Active Ingredients

<b>ascorbic acid</b>	<b>250 mg</b>
<b>betacarotene</b>	<b>3 mg</b>
<b>calcium pantothenate</b>	<b>28 mg</b>
Equivalent: pantothenic acid	25.7 mg
<b>d-alpha-tocopheryl acid succinate</b>	<b>41.3 mg</b>
<b>Echinacea purpurea</b>	<b>100 mg</b>
Equivalent: Echinacea purpurea	600 mg
<b>pyridoxine hydrochloride</b>	<b>13 mg</b>
Equivalent: pyridoxine	10.7 mg
<b>zinc amino acid chelate</b>	<b>6.5 mg</b>
Equivalent: zinc	1.3 mg

#### Other Ingredients (Excipients)

**ascorbyl palmitate**  
**calcium hydrogen phosphate dihydrate**  
**Carnauba Wax**  
**colloidal anhydrous silica**  
**croscarmellose sodium**  
**dl-alpha-tocopherol**  
**ethylcellulose**  
**Gelatin**  
**hypromellose**  
**iron oxide red**  
**macrogol 8000**  
**magnesium stearate**  
**Maize Oil**  
**maize starch**  
**microcrystalline cellulose**  
**sucrose**  
**titanium dioxide**

Public Summary

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