



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322405	BLACKMORES ECHINACEA ACE + ZINC
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	28/08/2019	
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 . BLACKMORES ECHINACEA ACE + ZINC

Product Type	Single Medicine Product	Effective Date	28/08/2019
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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 help 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 help reduce occurrence of symptoms of upper respiratory tract infections

Indication Requirements

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

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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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).
 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).
 Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

ascorbic acid	250 mg
betacarotene	3 mg
calcium pantothenate	28 mg
Equivalent: pantothenic acid	25.7 mg
d-alpha-tocopheryl acid succinate	41.3 mg
Echinacea purpurea root Extract dry concentrate	100 mg
Equivalent: Echinacea purpurea (Dry)	600 mg
pyridoxine hydrochloride	13 mg
Equivalent: pyridoxine	10.7 mg
zinc amino acid chelate	6.5 mg
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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