# Public Summary

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| **Summary for ARTG Entry:** | 312424 | BLACKMORES BIO C 1000 + EFFERVESCENT |
| **ARTG entry for** | Medicine Listed | |
| **Sponsor** | Blackmores Ltd | |
| **Postal Address** | PO Box 1725, WARRIEWOOD, NSW, 2102<br>Australia | |
| **ARTG Start Date** | 12/12/2018 | |
| **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.

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 BIO C 1000 + EFFERVESCENT

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| **Product Type** | Single Medicine Product | **Effective Date** | 19/08/2019 |

#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support collagen formation

Maintain/support general health and wellbeing

Maintain/support immune system health

Traditionally used in Native American medicine to maintain/support immune system health

Maintain/support healthy immune system function

Traditionally used in Native American medicine to maintain/support healthy immune system function

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Decrease/reduce/relieve common cold duration

Helps decrease/reduce/relieve the severity of symptoms of common colds and flu

Maintain/support wound healing

#### Indication Requirements

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

Label statement: If symptoms persist, talk to your health professional.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

**Additional Product information**

**Pack Size/Poison information**

| Pack Size | Poison Schedule |
|---|---|

**Components**

**1 . Formulation 1**

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| **Dosage Form** | Tablet, effervescent |
| **Route of Administration** | Oral |
| **Visual Identification** | |

**Active Ingredients**

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| **ascorbic acid** | **1 g** |
| **Echinacea purpurea herb top flowering Extract dry concentrate** | **50 mg** |
| Equivalent: Echinacea purpurea (Fresh) | 300 mg |
| **zinc gluconate** | **34.8 mg** |
| Equivalent: zinc | 5 mg |

**Other Ingredients (Excipients)**

**Beta vulgaris**
**citric acid**
**Flavour**
**leucine**
**maltodextrin**
**polysorbate 20**
**riboflavin sodium phosphate**
**simethicone**
**sodium bicarbonate**
**sodium carbonate**
**sorbitol**
**Steviol glycosides**

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