Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321636	BLACKMORES ECHINACEA FORTE

ARTG entry for	Medicine Listed
Sponsor	Blackmores Ltd
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia
ARTG Start Date	12/08/2019
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.

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 FORTE

Product Type	Single Medicine Product	**Effective Date**	17/12/2021

Permitted Indications

Maintain/support healthy lymphatic system

Maintain/support immune system health

Maintain/support healthy immune system function

Decrease/reduce/relieve common cold duration

Decrease/reduce/relieve the severity of common cold symptoms

Decrease/reduce/relieve symptoms of common cold

Indication Requirements

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

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 cardiovascular conditions.

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

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

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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).

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 purpurea herb Juice dry	**66.7 mg**
Equivalent: Echinacea purpurea (Fresh)	3 g

Other Ingredients (Excipients)

calcium hydrogen phosphate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
purified talc
soy polysaccharide