



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

## Public Summary

<b>Summary for ARTG Entry:</b>	331431	Echinamide Immune Bursts
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	18/03/2020	
<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.

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 . Echinamide Immune Bursts

Product Type	Single Medicine Product	Effective Date	18/03/2020
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### Permitted Indications

- Maintain/support immune system health
- Enhance/improve/promote immune defence/immunity
- Helps enhance/improve/promote immune system function
- Maintain/support immune system to fight illness
- Helps stimulate a healthy immune system response
- Decongestant/relieve nasal congestion
- Helps reduce occurrence of common colds
- Decrease/reduce/relieve common cold duration
- Helps decrease/reduce/relieve the severity of symptoms of common colds and flu
- Decrease/reduce/relieve symptoms of common colds and flu
- Decrease/reduce/relieve symptoms of head cold
- Decrease/reduce/relieve mild upper respiratory tract congestion
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Helps soothe respiratory tract
- Decrease/reduce/relieve the severity of common cold symptoms
- Relieve symptoms of mild upper respiratory tract infections
- Helps reduce occurrence of symptoms of upper respiratory tract infections
- Decrease/reduce/relieve cough
- Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Relieve symptoms of sore throat/pharyngitis

### Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.



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Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

Respiratory tract infections must be qualified by 'mild'.

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Adults only.

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

Not suitable for infants under the age of twelve months (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Echinacea purpurea whole plant Extract dry concentrate</b>	<b>85 mg</b>
Equivalent: Echinacea purpurea (Dry)	595 mg

**Other Ingredients (Excipients)**

- Eucalyptus Oil**
- Gelatin**
- glycerol**
- Honey**
- Lemon Oil**
- medium chain triglycerides**
- menthol**
- microcrystalline cellulose**
- Orange Oil**
- Peppermint Oil**
- purified water**
- xylitol**

Public Summary

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