



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

## Public Summary

<b>Summary for ARTG Entry:</b>	342620	INNER HEALTH SKIN SHIELD
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	31/08/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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 . INNER HEALTH SKIN SHIELD

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	31/08/2020
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### Permitted Indications

Helps reduce occurrence of symptoms of mild allergies in children  
Helps reduce occurrence of symptoms of acne when sun exposure is inadequate  
Decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis when sun exposure is inadequate in children  
Decrease/reduce/relieve symptoms of mild eczema/dermatitis when sun exposure is inadequate in children  
Helps reduce occurrence of symptoms of eczema/dermatitis in children  
Helps reduce occurrence of symptoms of eczema/dermatitis when sun exposure is inadequate in children  
Decrease/reduce/relieve skin irritation  
Decrease/reduce/relieve skin irritation when sun exposure is inadequate  
Maintain/support skin health when sun exposure is inadequate  
Maintain/support skin health  
Maintain/support wound healing when sun exposure is inadequate  
Maintain/support skin repair/healing/regeneration when sun exposure is inadequate

### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.  
Product presentation must only refer to mild eczema.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
If symptoms persist consult your healthcare practitioner (or words to that effect).

### Additional Product information

### Pack Size/Poison information



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

Pack Size

Poison Schedule

**Components**

1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium animalis ssp lactis</b>	<b>6 billion CFU</b>
<b>colecalfiferol</b>	<b>.025 mg</b>
<b>Lactobacillus rhamnosus</b>	<b>20 billion CFU</b>

**Other Ingredients (Excipients)**

**Acacia**

**disodium edetate**

**dl-alpha-tocopherol**

**gellan gum**

**hypromellose**

**magnesium stearate**

**maize starch**

**maltodextrin**

**medium chain triglycerides**

**microcrystalline cellulose**

**potable water**

**potassium acetate**

**silicon dioxide**

**sodium ascorbate**

**sucrose**

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