



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

## Public Summary

<b>Summary for ARTG Entry:</b>	353838	ETHICAL NUTRIENTS LYSINE COLD SORE DEFENCE
<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>	29/01/2021	
<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.

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 . ETHICAL NUTRIENTS LYSINE COLD SORE DEFENCE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/01/2021
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

Maintain/support collagen formation  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Aids/assists the body to cope with environmental stress  
Helps reduce occurrence of facial cold sores  
Maintain/support skin health  
Maintain/support wound healing  
Maintain/support skin repair/healing/regeneration

#### Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.  
Label statement: If symptoms persist, talk to your health professional.

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

#### Components

Public Summary



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

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>250 mg</b>
<b>Astragalus membranaceus root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Astragalus membranaceus (Dry)	2 g
<b>lysine hydrochloride</b>	<b>800 mg</b>
<b>zinc sulfate monohydrate</b>	<b>32.93 mg</b>
Equivalent: zinc	12 mg

**Other Ingredients (Excipients)**

**croscarmellose sodium**  
**glycerol**  
**hypromellose**  
**magnesium stearate**  
**microcrystalline cellulose**  
**silicon dioxide**

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary