



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

## Public Summary

<b>Summary for ARTG Entry:</b>	279410	Imrex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	22/08/2016	
<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 . Imrex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	15/10/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support body mucous membrane health  
Maintain/support general health and wellbeing  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract  
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: [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).

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

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for



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men.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

The recommended dose of this medicine provides small amounts of caffeine

#### Additional Product information

#### Pack Size/Poison information

**Pack Size** **Poison Schedule**

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

<b>Camellia sinensis leaf Extract dry concentrate standardised</b>	<b>166.67 mg</b>
Equivalent: Camellia sinensis (Dry)	2 g
<b>colecalfiferol</b>	<b>.0125 mg</b>
<b>curcumin</b>	<b>23.08 mg</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>123.967 mg</b>
Equivalent: d-alpha-tocopherol	150 IU
<b>Ganoderma lucidum fruiting body Extract dry concentrate</b>	<b>37.5 mg</b>
Equivalent: Ganoderma lucidum (Dry)	750 mg
<b>Lentinula edodes fruiting body Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Lentinula edodes (Dry)	1.5 g
<b>retinol palmitate</b>	<b>2.3375 mg</b>
Equivalent: vitamin A	1275.93 RE
<b>selenomethionine</b>	<b>187.5 microgram</b>
Equivalent: selenium	75 microgram
<b>Trametes versicolor fruiting body Extract dry concentrate</b>	<b>65 mg</b>
Equivalent: Trametes versicolor (Dry)	650 mg
<b>zinc citrate dihydrate</b>	<b>23.438 mg</b>
Equivalent: zinc	7.5 mg

#### Other Ingredients (Excipients)

Acacia  
butylated hydroxytoluene  
calcium hydrogen phosphate  
colloidal anhydrous silica  
disodium edetate  
dl-alpha-tocopherol  
gellan gum  
hypromellose  
maize starch  
maltodextrin  
medium chain triglycerides  
Oryza sativa  
potable water  
potassium acetate  
silicon dioxide  
stearic acid

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**sucrose**

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