



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- 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).
- 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

- 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.



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

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

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

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

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