



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	333731	Adalase
<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>	8/04/2020	
<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 . Adalase

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/04/2020
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### Permitted Indications

Maintain/support healthy eye function  
Maintain/support eye health  
Helps maintain/support eye retina health  
Maintain/support healthy eyesight/vision  
Maintain/support body mucous membrane health  
Maintain/support general health and wellbeing  
Maintain/support bone health  
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

### Indication Requirements

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

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

### Standard Indications

No Standard Indications included on Record



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**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

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.

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

Dosage Form                      Tablet, chewable

Route of Administration      Oral

**Visual Identification**

**Active Ingredients**

Amylase	63.4 mg
colecalfiferol	.0095 mg
papain	190 mg
retinol acetate	3.3615 mg

**Other Ingredients (Excipients)**

Acacia  
beetroot  
carmellose sodium  
colloidal anhydrous silica  
d-alpha-tocopherol  
dl-alpha-tocopherol  
Flavour  
fractionated coconut oil  
liquid glucose  
magnesium stearate  
maize starch  
maltodextrin  
microcrystalline cellulose  
silicon dioxide  
sodium ascorbate  
spray-dried glucose syrup  
xylitol

Public Summary

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