



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	386776	HistEase
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	5/04/2022 11:00:00 PM	
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 . HistEase

Product Type	Single Medicine Product	Effective Date	6/04/2022
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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 eye health
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Maintain/support blood capillary health
Maintain/support gastrointestinal mucosal membrane health
Helps decrease/reduce/relieve mild gastrointestinal tract inflammation
Helps decrease/reduce/relieve symptoms of mild allergies
Decrease/reduce/relieve symptoms of allergic rhinitis in children
Decrease/reduce/relieve symptoms of allergic rhinitis in adults
Helps reduce occurrence of symptoms of mild allergies
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to serious immunological diseases.
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

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.

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

Nigella sativa seed Oil fixed	450 mg
quercetin	300 mg
retinol palmitate	102.85 microgram
Equivalent: vitamin A	56.1 RE
rutoside	125 mg

Other Ingredients (Excipients)

chlorophyllin-copper complex

dl-alpha-tocopherol

Gelatin

glycerol

lecithin

purified water

Rice bran oil

yellow beeswax

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