



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351359	Eagle Beta A-C Tablets
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	9/12/2020	
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 . Eagle Beta A-C Tablets

Product Type	Single Medicine Product	Effective Date	23/02/2021
--------------	-------------------------	----------------	------------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body in aging individuals
- Antioxidant/Reduce free radicals formed in the body in adolescents
- Helps reduce/decrease free radical damage to body cells
- Helps reduce/decrease free radical damage to body cells in adolescents
- Helps reduce/decrease free radical damage to body cells in aging individuals
- Maintain/support collagen formation in aging individuals
- Maintain/support collagen formation in adolescents
- Maintain/support collagen formation
- Maintain/support collagen health in aging individuals
- Maintain/support collagen health in adolescents
- Maintain/support collagen health
- Maintain/support general health and wellbeing in aging individuals
- Maintain/support general health and wellbeing in adolescents
- Maintain/support general health and wellbeing
- Aid/assist/helps connective tissue production/formation in aging individuals
- Aid/assist/helps connective tissue production/formation
- Aid/assist/helps connective tissue production/formation in adolescents
- Maintain/support body tissue repair/regeneration in adolescents
- Maintain/support body tissue repair/regeneration
- Maintain/support body tissue repair/regeneration in aging individuals
- Maintain/support artery health in adolescents
- Maintain/support artery health in aging individuals
- Maintain/support artery health
- Maintain/support blood capillary health in aging individuals
- Maintain/support blood capillary health in adolescents
- Maintain/support blood capillary health



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

- Maintain/support blood vessel health
- Maintain/support blood vessel health in adolescents
- Maintain/support blood vessel health in aging individuals
- Maintain/support immune system health in aging individuals
- Maintain/support immune system health
- Maintain/support immune system health in adolescents
- Maintain/support healthy immune system function in adolescents
- Maintain/support healthy immune system function in aging individuals
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support immune system to fight illness in adolescents
- Maintain/support immune system to fight illness in aging individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range in adolescents
- Maintain/support (state vitamin/mineral) within normal range in aging individuals
- Support healthy stress response in the body in adolescents
- Support healthy stress response in the body
- Support healthy stress response in the body in aging individuals
- Decrease/reduce/relieve common cold duration in adolescents
- Decrease/reduce/relieve common cold duration in aging individuals
- Decrease/reduce/relieve common cold duration
- Decrease/reduce/relieve symptoms of common colds and flu
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve symptoms of common colds and flu in aging individuals
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve symptoms of common colds and flu in adolescents
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in adolescents
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in aging individuals
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve the severity of common cold symptoms in adolescents
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation



Australian Government
Department of Health
 Therapeutic Goods Administration

- Decrease/reduce/relieve the severity of common cold symptoms in aging individuals
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Decrease/reduce/relieve the severity of common cold symptoms
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Relieve symptoms of mild upper respiratory tract infections
- Relieve symptoms of mild upper respiratory tract infections in adolescents
- Relieve symptoms of mild upper respiratory tract infections in aging individuals
- Maintain/support skin health
- Maintain/support skin health in adolescents
- Maintain/support skin health in aging individuals
- Maintain/support wound healing in aging individuals
- Maintain/support wound healing in adolescents
- Maintain/support wound healing
- Maintain/support skin repair/healing/regeneration in aging individuals
- Maintain/support skin repair/healing/regeneration
- Maintain/support skin repair/healing/regeneration in adolescents

Indication Requirements

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
 Respiratory tract infections must be qualified by 'mild'.
 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

If symptoms persist, seek the advice of a healthcare professional.
 For practitioner dispensing only.
 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

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	589 mg
calcium ascorbate dihydrate	104.67 mg
Equivalent: ascorbic acid	84 mg
Equivalent: calcium	9.54 mg
Citrus bioflavonoids extract	50 mg
d-alpha-tocopheryl acid succinate	41.376 mg



Australian Government
Department of Health
Therapeutic Goods Administration

Dunaliella salina cell Extract soft concentrate standardised	7 mg
Equivalent: Dunaliella salina (Fresh)	13.125 mg
rutoside	150 mg
sodium ascorbate	146.62 mg
Equivalent: ascorbic acid	127.73 mg
Equivalent: sodium	17.7 mg
zinc amino acid chelate	10 mg
Equivalent: zinc	2 mg

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
crospovidone
Gelatin
hypromellose
magnesium stearate
maize starch
microcrystalline cellulose
mixed (low-alpha type) tocopherols concentrate
potable water
riboflavin
silicon dioxide
Soya Oil
sucrose

© 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