



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	229911	Eagle CytoPro Repair
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	29/10/2014	
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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Eagle CytoPro Repair

Product Type	Single Medicine Product	Effective Date	28/10/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Ayurvedic medicine to maintain/support healthy digestion
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support gastrointestinal mucosal membrane health
- Aids/assists repair of gastrointestinal/gut wall lining
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Helps stimulate a healthy immune system response
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

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Maintain/support (state vitamin/mineral) within normal range

Indication Requirements

Label statement: 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.

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

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

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.

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Actinidia deliciosa	25 mg/g
Equivalent: Actinidia deliciosa	125 mg/g
Actinidia deliciosa	25 mg/g
Equivalent: Actinidia deliciosa	1.25 g/g
Aloe vera	5 mg/g
Equivalent: Aloe vera	1 g/g
Equivalent: Hydroxyanthracene derivatives calculated as anhydrous barbaloin	50 microgram/g
Brassica oleracea var. italica	15 mg/g
Equivalent: Brassica oleracea var. italica	300 mg/g
colecalfiferol	1 microgram/g
Curcuma longa	12 mg/g
Equivalent: curcuminoids	11.4 mg/g
Equivalent: Curcuma longa	300 mg/g
glutamine	400 mg/g
Glycyrrhiza glabra	15 mg/g
Larix arabinogalactan	150 mg/g
pectin	20 mg/g
retinol acetate	.2122 mg/g

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zinc citrate dihydrate 6.231 mg/g
Equivalent: zinc 2 mg/g

Other Ingredients (Excipients)

Acacia
ascorbic acid
beetroot
Beta vulgaris
Black currant
Blackberry
citric acid
colloidal anhydrous silica
Cranberry
dl-alpha-tocopherol
Flavour
glycine
Hippophae rhamnoides
maize starch
Malpighia glabra
maltodextrin
medium chain triglycerides
Pomegranate
Raspberry
Salvia hispanica
Sambucus nigra
silicon dioxide
Stevia rebaudiana
Strawberry
sucrose
tapioca starch
thaumatin
Vaccinium myrtillus

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