



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 330532 Eagle PathoClear 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	27/02/2020
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 PathoClear Tablets

Product Type	Single Medicine Product	Effective Date	30/04/2021
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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 general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to orexigenic/improve/promote healthy appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms
- Traditionally used in Western herbal medicine to enhance/promote healthy digestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
 - Linked indication - Decrease/reduce/relieve nausea
 - Linked indication - Decrease/reduce/relieve abdominal spasm
 - Linked indication - Decrease/reduce/relieve abdominal cramping
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
 - Linked indication - Decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Relieve feelings of general malaise/general debility
 - Linked indication - Relieve runny/dripping nose
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold

Indication Requirements

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

Respiratory tract infections must be qualified by 'mild'.

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

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to eating disorders.

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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.

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

Do not use if pregnant or likely to become pregnant (or words to that effect)

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Allium sativum bulb Extract dry concentrate	57 mg
Equivalent: Allium sativum (Fresh)	684 mg
Cinnamomum verum stem bark outer Extract dry concentrate	41.7 mg
Equivalent: Cinnamomum verum (Dry)	500 mg
Clove Bud Oil	5 mg
Nigella sativa seed Extract dry concentrate	200 mg
Equivalent: Nigella sativa (Dry)	1 g
Phellodendron amurense stem bark Extract dry concentrate standardised	280 mg
Equivalent: Phellodendron amurense (Dry)	5.6 g
Thyme Oil	5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
dextrin
dl-alpha-tocopherol



Australian Government

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Garlic Bulb Powder
hydrochloric acid
hypromellose
magnesium stearate
microcrystalline cellulose
silicon dioxide

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