

Australian Government

Department of Health and Aged Care

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 23/04/2025

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 flatulence/carminative Linked indication - Decrease/reduce/relieve abdominal cramping Linked indication - Decrease/reduce/relieve abdominal spasm

Linked indication - Decrease/reduce/relieve nausea

Linked indication - Decrease/reduce/relieve abdominal bloating/distention

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 - Relieve feelings of general malaise/general debility

Linked indication - Decrease/reduce/relieve sneezing Linked indication - Decrease/reduce/relieve cough 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

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

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

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

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

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

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 other worms e.g. roundworm, tapeworm, hookworm.

Respiratory tract infections must be qualified by 'mild'.

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 serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

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).

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

Adults only. OR Not to be used in children under two years of age without 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).

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

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

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

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