



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	210683	ParaStrike
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	7/06/2013	
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 . ParaStrike

Product Type	Single Medicine Product	Effective Date	8/11/2021
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation

Traditionally used in Western herbal medicine to aperient/laxative

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 decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to maintain/support healthy liver function

Indication Requirements

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

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

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).

Label statement: Drink plenty of water (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 gastro oesophageal reflux disease.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not refer to or imply weight loss.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

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



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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

Artemisia absinthium leaf Extract dry concentrate	50 mg
Equivalent: Artemisia absinthium (Dry)	500 mg
Berberis vulgaris root bark Extract dry concentrate	25 mg
Equivalent: Berberis vulgaris (Dry)	150 mg
Juglans nigra fruit hull Extract dry concentrate	15 mg
Equivalent: Juglans nigra (Dry)	150 mg
Origanum vulgare herb flowering Oil essential	25 mg
Thymus vulgaris leaf Oil essential	8 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
crospovidone
glucose monohydrate
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

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