#### **Australian Government**

## Department of Health, Disability and Ageing

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 210683 Wormwood Clear

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

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. Wormwood Clear

Product Type Single Medicine Product Effective Date 2/09/2025

## 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: If symptoms persist, talk to your health professional.

Label statement: Drink plenty of water (or words to that effect).

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).

Product presentation must not refer to or imply weight loss.

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

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 liver disease, such as cirrhosis, hepatitis.

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

Contains sugars

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

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## **Additional Product information**

		ormation

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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