



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	221765	Candida Relief
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	27/03/2014	
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.

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 . Candida Relief

Product Type	Single Medicine Product	Effective Date	7/07/2021
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Permitted Indications

Traditionally used in South American medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Traditionally used in South American medicine to maintain/support gastrointestinal system health

Maintain/support immune system health

Maintain/support healthy immune system function

Traditionally used in South American medicine to decrease/reduce/relieve symptoms of mild, superficial skin fungal infections

Indication Requirements

Label statement: Not to be used in children under 5 years.

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

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

Product presentation must only refer to mild fungal infection.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
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Route of Administration Oral

Visual Identification

Active Ingredients

Handroanthus impetiginosus stem bark inner Extract dry concentrate	250 mg
Equivalent: Handroanthus impetiginosus (Dry)	1 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
copovidone
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
sodium starch glycollate

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