



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	119573	COSTAT
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	30/05/2005	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

The warning statement 'Do not use if pregnant or likely to become pregnant' must be displayed on the medicine label.

### Products

#### 1 . COSTAT

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/01/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Traditionally used in Chinese medicine to vermifuge/helps remove intestinal threadworms/pinworms  
Traditionally used in Western herbal medicine to maintain/support healthy digestive system function  
Traditionally used in Chinese medicine to maintain/support healthy digestive system function  
Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions  
Traditionally used in Chinese medicine to bitter tonic/stimulate gastric secretions

### Indication Requirements

Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.  
Label statement: If symptoms persist, talk to your health professional.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Do not use if pregnant or likely to become pregnant (or words to that effect)  
If symptoms persist consult your healthcare practitioner (or words to that effect).

### Additional Product information

### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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### Components

#### 1 . Formulation 1

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**Dosage Form**                    Tablet, film coated

**Route of Administration**    Oral

**Visual Identification**

**Active Ingredients**

<b>Artemisia annua whole plant Extract dry concentrate</b>	<b>375 mg</b>
Equivalent: Artemisia annua (Dry)	3 g
<b>Olea europaea leaf Extract dry concentrate</b>	<b>75 mg</b>
Equivalent: Olea europaea (Dry)	750 mg

**Other Ingredients (Excipients)**

carrageenan

croscarmellose sodium

macrogol 8000

microcrystalline cellulose

powdered cellulose

silicon dioxide

stearic acid

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