



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

## Public Summary

<b>Summary for ARTG Entry:</b>	286503	METAGENICS BACTREX
<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>	8/03/2017	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . METAGENICS BACTREX

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/04/2020
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

Traditionally used in Chinese medicine to maintain/support small intestine health  
Traditionally used in Chinese medicine to maintain/support intestinal health  
Vermifuge/helps remove intestinal threadworms/pinworms  
Traditionally used in Chinese medicine to maintain/support gastrointestinal system health

#### 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

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>
------------------	------------------------

#### Components

1 . Formulation 1

Public Summary



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

**Dosage Form** Capsule soft enteric

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Origanum vulgare leaf Oil essential</b>	<b>100 mg</b>
<b>Phellodendron amurense stem bark Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Phellodendron amurense (Dry)	750 mg
<b>Syzygium aromaticum leaf Oil essential</b>	<b>50 mg</b>
<b>Thymus vulgaris herb flowering Oil essential</b>	<b>50 mg</b>

**Other Ingredients (Excipients)**

Carnauba Wax

Colour

Gelatin

glycerol

lecithin

methacrylic acid copolymer

mono- and di- glycerides

polysorbate 80

propylene glycol

purified water

sodium lauryl sulfate

Soya Oil

yellow beeswax

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary