



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

## Public Summary

<b>Summary for ARTG Entry:</b>	216454	Charcoal Max
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	PremaLife Pty Ltd t/a Natural Vitality Australia	
<b>Postal Address</b>	11 Aldinga Street, BRENDALE, QLD, 4500 Australia	
<b>ARTG Start Date</b>	23/10/2013	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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 . Charcoal Max

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/08/2019
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#### Permitted Indications

Decrease/reduce/relieve flatulence/carminative  
Decrease/reduce/relieve abdominal bloating/distention  
Decrease/reduce/relieve symptoms of indigestion/dyspepsia

#### Indication Requirements

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

Products containing activated charcoal should be used with caution in children since it may interfere with absorption of nutrients. Activated charcoal may interact with other medicines. Activated charcoal is not recommended for long-term use. [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

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

#### Visual Identification

#### Active Ingredients

activated charcoal	250 mg
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<b>Carica papaya fruit Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Carica papaya (Fresh)	1.5 g
<b>Foeniculum vulgare fruit Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Foeniculum vulgare (Dry)	200 mg
<b>Peppermint Oil</b>	<b>4 mg</b>
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>44 mg</b>
Equivalent: Zingiber officinale (Fresh)	220 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
Gelatin  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
purified water  
silicon dioxide  
sodium lauryl sulfate

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