Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type Single Medicine Product **Effective Date** 28/08/2019

Permitted Indications

Decrease/reduce/relieve flatulence/carminative

Decrease/reduce/relieve abdominal bloating/distention

Decrease/reduce/relieve symptoms of indigestion/dyspepsia

Indication Requirements

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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).

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]

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

activated charcoal **250 mg**

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Carica papaya fruit Extract dry concentrate	**100 mg**
Equivalent: Carica papaya (Fresh)	1.5 g
Foeniculum vulgare fruit Extract dry concentrate	**40 mg**
Equivalent: Foeniculum vulgare (Dry)	200 mg
Peppermint Oil	**4 mg**
Zingiber officinale rhizome Extract dry concentrate	**44 mg**
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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