Public Summary

Summary for ARTG Entry:	281763 Phytaxil
ARTG entry for	Medicine Listed
Sponsor	Biomedica Nutraceuticals Pty Ltd
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	26/10/2016
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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Phytaxil

Product Type Single Medicine Product **Effective Date** 15/08/2019

Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to vermifuge/helps remove intestinal threadworms/pinworms

Traditionally used in Western herbal medicine to maintain/support digestive system health

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion

Traditionally used in Western herbal medicine to unblock/clear nasal passages

Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections

Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous

Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

Indication Requirements

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to other worms e.g. roundworm, tapeworm, hookworm.

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

Adults only. OR Not to be used in children under two years of age without medical advice (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

Allium sativum	**60 mg**
Equivalent: Allium sativum	1.2 mg
Commiphora myrrha	**25 mg**
Equivalent: Commiphora myrrha	250 mg
Origanum vulgare	**50 mg**
Phellodendron amurense	**100 mg**
Equivalent: Phellodendron amurense	2 g
Equivalent: berberine	47.5 mg
Thymus vulgaris	**60 mg**
Equivalent: Thymus vulgaris	600 mg

Other Ingredients (Excipients)

Acacia
colloidal anhydrous silica
disodium edetate
gellan gum
hydrochloric acid
hypromellose
maltodextrin
microcrystalline cellulose
potable water
potassium acetate
stearic acid

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