



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	290659	Paracea Forte
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	26/06/2017	
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.

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 . Paracea Forte

Product Type	Single Medicine Product	Effective Date	6/10/2021
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite

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

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

Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions

Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm

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

Antiemetic/Decrease/reduce/relieve vomiting

Indication Requirements

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

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

Product presentation must not imply or refer to eating disorders.

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

Do not use if pregnant or likely to become pregnant (or words to that effect)

Individuals taking anticoagulants should seek medical advice before taking this product. AND Individuals at risk of bleeding problems should seek advice from their health practitioner prior to taking this product.

Additional Product information



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Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, enteric coated

Route of Administration Oral

Visual Identification

Active Ingredients

Artemisia annua herb Extract dry concentrate standardised	187.5 mg
Equivalent: Artemisia annua (Dry)	750 mg
Berberis vulgaris root Extract dry concentrate standardised	125 mg
Equivalent: Berberis vulgaris (Dry)	750 mg
Citrus X paradisi fruit Extract dry concentrate	18 mg
Equivalent: Citrus X paradisi (Dry)	450 mg
Clove Powder	50 mg
Juglans nigra fruit hull Extract dry concentrate	40 mg
Equivalent: Juglans nigra (Dry)	400 mg
Zingiber officinale root Extract dry concentrate standardised	25 mg
Equivalent: Zingiber officinale (Dry)	500 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
ethylcellulose
hypromellose
macrogol 400
magnesium stearate
maltodextrin
medium chain triglycerides
microcrystalline cellulose
oleic acid
povidone
purified water
sodium alginate
stearic acid
strong ammonia solution

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