



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

## Public Summary

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

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

|                     |                         |                       |           |
|---------------------|-------------------------|-----------------------|-----------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 6/10/2021 |
|---------------------|-------------------------|-----------------------|-----------|

#### 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**

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

Public Summary

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