



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

## Public Summary

<b>Summary for ARTG Entry:</b>	370078	MediHerb Bilberry Forte
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	23/06/2021	
<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 . MediHerb Bilberry Forte

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/10/2021
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support general health and wellbeing
- Maintain/support blood capillary health
- Traditionally used in Western herbal medicine to decrease/relieve symptoms of haemorrhoids
  - Linked indication - Decrease/relieve discomfort associated with haemorrhoids
- Traditionally used in Western herbal medicine to decrease/relieve symptoms of haemorrhoids
- Traditionally used in Western herbal medicine to decrease/relieve discomfort associated with haemorrhoids
- Traditionally used in Western herbal medicine to decrease/relieve symptoms of mild varicose veins
- Traditionally used in Western herbal medicine to decrease/relieve aching/tired legs/leg heaviness associated with mild varicose veins
- Traditionally used in Western herbal medicine to decrease/relieve diarrhoea
- Traditionally used in Western herbal medicine to decrease/relieve loose stools

### Indication Requirements

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).

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

Product presentation must only refer to mild varicose veins.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

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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).

**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**

<b>Vaccinium myrtillus fruit Extract dry concentrate standardised</b>	<b>120 mg</b>
Equivalent: Vaccinium myrtillus (Fresh)	12 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
purified water  
sodium starch glycollate

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