



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	219770	Migraine Care
<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 Australia	
<b>ARTG Start Date</b>	31/01/2014	
<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 . Migraine Care

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/11/2021
---------------------	-------------------------	-----------------------	-----------

### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support energy production  
Aid/assist healthy red blood cell production  
Maintain/support red blood cell health  
Support healthy stress response in the body when dietary intake is inadequate  
Helps reduce occurrence of mild migraines  
Decrease/reduce duration of mild migraine  
Maintain/support nerve conduction  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system function

### Indication Requirements

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

Product presentation must only refer to mild migraine.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Do not take while on warfarin therapy without medical advice.

### Additional Product information



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium folinate</b>	<b>347.2 microgram</b>
Equivalent: folic acid	250 microgram
<b>cyanocobalamin</b>	<b>200 microgram</b>
<b>magnesium citrate</b>	<b>928.22 mg</b>
Equivalent: magnesium	150 mg
<b>pyridoxine hydrochloride</b>	<b>15.19 mg</b>
Equivalent: pyridoxine	12.5 mg
<b>riboflavin</b>	<b>200 mg</b>
<b>Tanacetum parthenium herb Extract dry concentrate standardised</b>	<b>40 mg</b>
Equivalent: Tanacetum parthenium (Dry)	280 mg
<b>ubidecarenone</b>	<b>75 mg</b>

**Other Ingredients (Excipients)**

**Carnauba Wax**

**chlorophyllin-copper complex**

**colloidal anhydrous silica**

**croscarmellose sodium**

**crospovidone**

**hypromellose**

**macrogol 8000**

**magnesium stearate**

**microcrystalline cellulose**

**povidone**

**titanium dioxide**

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary