



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	219770	Migraine Care
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	31/01/2014	
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 . Migraine Care

Product Type	Single Medicine Product	Effective Date	5/11/2021
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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
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

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

Other Ingredients (Excipients)

Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
povidone
titanium dioxide

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