



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	212998	NuroSAmE Plus
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	7/08/2013	
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 . NuroSAmE Plus

Product Type	Single Medicine Product	Effective Date	8/12/2021
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Permitted Indications

Maintain/support natural liver cleansing/detoxification processes
Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
Anti-inflammatory/relieve inflammation
Aid/assist healthy red blood cell production
Maintain/support liver health
Helps decrease/reduce homocysteine levels
Aid/assist/helps synthesis of neurotransmitters
Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must only refer to detoxification in relation to natural body processes.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to drugs/alcohol.
Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect).



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Additional Product information

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

ademetionine disulfate tosylate	412.37 mg
Equivalent: (S)-S-adenosylmethionine	146.97 mg
calcium folinate	173.6 microgram
Equivalent: folinic acid	125 microgram
cyanocobalamin	.05 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate
Carnauba Wax
cellulose
colloidal anhydrous silica
croscarmellose sodium
crospovidone
diethyl phthalate
glyceryl behenate
hypromellose
magnesium stearate
mannitol
microcrystalline cellulose
titanium dioxide
vanillin

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