



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311464	SAMe 400 Complex
ARTG entry for	Medicine Listed	
Sponsor	Nutrition Care Pharmaceuticals Pty Ltd	
Postal Address	25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia	
ARTG Start Date	13/11/2018	
Product Category	Medicine	
Status	Active	
Approval Area	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 . SAMe 400 Complex

Product Type	Single Medicine Product	Effective Date	13/11/2018
--------------	-------------------------	----------------	------------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy levels
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues
- Maintain/support bone health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Help maintain/support emotional wellbeing
- Maintain/support cognitive function/mental function in healthy adults
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

- Maintain/support nervous system health
- Maintain/support nervous system function
- Support healthy emotional/mood balance
- Maintain/support female reproductive system health
- Maintain/support reproductive system health in males
- Maintain/support healthy reproductive hormones
- Maintain/support sperm health in healthy males
- Maintain/support sperm production in healthy males
- Maintain/support testosterone level
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin regeneration
- Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to infertility.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to hormone imbalances.
 Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
 Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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).
 WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
 [Contains vitamin B6].
 Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

(S)-S-adenosylmethionine disulfate tosylate	800 mg
Equivalent: (S)-S-adenosylmethionine	400 mg
cyanocobalamin	1 mg
folic acid	90 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg



Australian Government
Department of Health
Therapeutic Goods Administration

riboflavin	20 mg
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hydrogenated vegetable oil
hypromellose
magnesium stearate
methacrylic acid copolymer
microcrystalline cellulose
purified talc
sodium bicarbonate
sodium lauryl sulfate
stearic acid
titanium dioxide
triethyl citrate

© 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