



Australian Government

Department of Health, Disability and Ageing
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

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 . SAMe 400 Complex

Product Type	Single Medicine Product	Effective Date	27/06/2025
---------------------	-------------------------	-----------------------	------------

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 wound healing
Maintain/support skin regeneration
Maintain/support skin integrity/structure
Maintain/support skin health
Maintain/support testosterone level
Maintain/support sperm production in healthy males
Maintain/support sperm health in healthy males



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Maintain/support healthy reproductive hormones
Maintain/support reproductive system health in males
Maintain/support female reproductive system health
Support healthy emotional/mood balance
Maintain/support nervous system function
Maintain/support nervous system health
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nerve conduction
Maintain/support cognitive function/mental function in healthy adults
Help maintain/support emotional wellbeing
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)

Indication Requirements

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 serious cardiovascular conditions.

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

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 the table in Part 2 of Schedule 1 to 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).

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to hormone imbalances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

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].

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



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg
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