



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	343137	Swisse Nutra+ Advanced Mag Night
ARTG entry for	Medicine Listed	
Sponsor	Swisse Wellness Pty Ltd	
Postal Address	111 Cambridge Street, Collingwood, VIC, 3066 Australia	
ARTG Start Date	8/09/2020	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Swisse Nutra+ Advanced Mag Night

Product Type	Single Medicine Product	Effective Date	8/09/2020
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Permitted Indications

Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
Maintain/support muscle health
Maintain/support muscle function
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Maintain/support nervous system health
Maintain/support nervous system function
Traditionally used in Western herbal medicine to maintains/supports refreshing sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record



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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Eschscholzia californica herb top Extract dry concentrate	15.63 mg/g
Equivalent: Eschscholzia californica (Dry)	250 mg/g
glycine	213 mg/g
magnesium citrate nonahydrate	122.66 mg/g
Equivalent: magnesium	14.58 mg/g
magnesium glycinate dihydrate	250.16 mg/g
Equivalent: magnesium	29.17 mg/g
Passiflora incarnata flower and leaf Extract dry concentrate	7.5 mg/g
Equivalent: Passiflora incarnata (Dry)	375 mg/g

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
malic acid
maltodextrin
silicon dioxide
Siraitia grosvenorii
Stevia rebaudiana

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