Public Summary

Summary for ARTG Entry:	292278	NUTRA-LIFE MENO-LIFE DAY + NIGHT

ARTG entry for	Medicine Listed
Sponsor	Vitaco Health Australia Pty Ltd
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	1/08/2017
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'.

All products containing Cimicifuga racemosa must comply with the following condition of listing by carrying the label statement - Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

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 . NUTRA-LIFE MENO-LIFE DAY + NIGHT

Product Type	Composite Pack	**Effective Date**	24/02/2021

Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy

Traditionally used in Western herbal medicine to soothe/calm nerves

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Western herbal medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause

Linked indication - Decrease/reduce/relieve hot flushes associated with menopause

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

Additional Product information

Pack Size/Poison information	
Pack Size	**Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Actaea racemosa root and rhizome Extract dry concentrate	**50 mg**
Equivalent: Actaea racemosa (Dry)	500 mg
Angelica polymorpha root Extract dry concentrate	**71.43 mg**
Equivalent: Angelica polymorpha (Dry)	500 mg
calcium citrate tetrahydrate	**219.05 mg**
Equivalent: calcium	46 mg
Glycine max seed Extract dry concentrate	**50 mg**
Equivalent: Glycine max (Dry)	8 g
heavy magnesium oxide	**66.34 mg**
Equivalent: magnesium	40 mg
Passiflora incarnata herb Extract dry concentrate	**10 mg**
Equivalent: Passiflora incarnata (Dry)	50 mg
Trifolium pratense herb top flowering Extract dry concentrate	**37.5 mg**
Equivalent: Trifolium pratense (Dry)	150 mg
Valeriana officinalis root Extract dry concentrate	**166.67 mg**
Equivalent: Valeriana officinalis (Dry)	1 g
Vitex agnus-castus fruit Extract dry concentrate	**41.67 mg**
Equivalent: Vitex agnus-castus (Dry)	500 mg

Other Ingredients (Excipients)

glucose
hypromellose
magnesium stearate
maltodextrin
potable water
silicon dioxide
vanillin

2 . Formulation 2

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Actaea racemosa root and rhizome Extract dry concentrate	**50 mg**
Equivalent: Actaea racemosa (Dry)	500 mg
Angelica polymorpha root Extract dry concentrate	**71.43 mg**
Equivalent: Angelica polymorpha (Dry)	500 mg
calcium citrate tetrahydrate	**333.34 mg**
Equivalent: calcium	70 mg
Eleutherococcus senticosus root Extract dry concentrate standardised	**10 mg**
Equivalent: Eleutherococcus senticosus (Dry)	150 mg

Glycine max seed Extract dry concentrate	**50 mg**
Equivalent: Glycine max (Dry)	8 g
heavy magnesium oxide	**66.34 mg**
Equivalent: magnesium	40 mg
Hypericum perforatum herb top flowering Extract dry concentrate	**41.67 mg**
Equivalent: Hypericum perforatum (Dry)	250 mg
Trifolium pratense herb top flowering Extract dry concentrate	**37.5 mg**
Equivalent: Trifolium pratense (Dry)	150 mg
Vitex agnus-castus fruit Extract dry concentrate	**41.67 mg**
Equivalent: Vitex agnus-castus (Dry)	500 mg

Other Ingredients (Excipients)

glucose
hypromellose
magnesium stearate
maltodextrin
potable water
silicon dioxide
titanium dioxide

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