



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316046	De-Stress Ultra with Ashwagandha
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Limited	
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia	
ARTG Start Date	2/04/2019	
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 . De-Stress Ultra with Ashwagandha

Product Type	Single Medicine Product	Effective Date	17/02/2021
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Permitted Indications

Enhance/promote energy levels
Maintain/support energy levels
Maintain/support energy production
Helps enhance/promote/increase vitality
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support general health and wellbeing
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Enhance/promote body adaptation to stress
Support healthy body stress recovery
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Support healthy stress response in the body
Help maintain/support emotional wellbeing
Decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve symptoms of stress
Linked indication - Decrease/reduce/relieve sleeplessness
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Helps reduce occurrence of symptoms of mild anxiety

Indication Requirements

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

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

Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to mild anxiety.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased

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physical activity.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

calcium pantothenate	20 mg
Equivalent: pantothenic acid	18.3 mg
cyanocobalamin	5 microgram
nicotinamide	15 mg
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.1 mg
riboflavin	25 mg
Schisandra chinensis fruit Extract dry concentrate	150 mg
Equivalent: Schisandra chinensis (Dry)	1.5 g
thiamine hydrochloride	10 mg
Withania somnifera root Extract dry concentrate	300 mg
Equivalent: Withania somnifera (Dry)	3 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	100 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	1 g

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

silicon dioxide

sodium citrate dihydrate

sorbitol

starch sodium octenyl succinate

titanium dioxide

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