



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	316046	De-Stress Ultra with Ashwagandha
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytologic Holdings Pty Limited	
<b>Postal Address</b>	PO Box 6193, Alexandria, NSW, 2015 Australia	
<b>ARTG Start Date</b>	2/04/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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  
Decrease/reduce/relieve symptoms of stress  
Linked indication - Decrease/reduce/relieve sleeplessness  
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress  
Decrease/reduce/relieve nervous tension/unrest  
Traditionally used in Ayurvedic medicine to 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 chronic fatigue syndrome.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
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 physical activity.

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**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**

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