



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	354654	SuperFeast Ashwagandha
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JEMS Superfoods Pty Ltd trading as SuperFeast	
<b>Postal Address</b>	2/16-18 towers drive, mullumbimby, NSW, 2482 Australia	
<b>ARTG Start Date</b>	9/02/2021	
<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 . SuperFeast Ashwagandha

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	9/02/2021
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#### Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to enhance/promote energy levels
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to calms the mind
- Traditionally used in Ayurvedic medicine to enhance/promote/increase healthy sleep patterns
- Traditionally used in Ayurvedic medicine to maintain/support healthy reproductive hormones

#### Indication Requirements

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to hormone imbalances.

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

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

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

- 1 . Formulation 1

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**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Withania somnifera root Extract dry concentrate</b>	<b>500 mg</b>
Equivalent: Withania somnifera (Dry)	5 g

**Other Ingredients (Excipients)**

hypromellose

Phyllostachys nigra

purified water

Sweet potato

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