



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

## Public Summary

<b>Summary for ARTG Entry:</b>	186836	BLOOMS SUPER KELP capsules
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytologic Holdings Pty Ltd	
<b>Postal Address</b>	PO Box 6193, Alexandria, NSW, 2015 Australia	
<b>ARTG Start Date</b>	23/07/2011	
<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 . BLOOMS SUPER KELP capsules

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/02/2021
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### Permitted Indications

Maintain/support energy levels  
Maintain/support body metabolism/metabolic rate  
Maintain/support general health and wellbeing  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Maintain/support thyroid gland health  
Aid/assist thyroid hormone production  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

### Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.  
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).  
Product presentation must not imply or refer to chronic fatigue syndrome.  
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.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

If fluid retention persists, seek medical advice (or words to that effect).  
If symptoms persist consult your healthcare practitioner (or words to that effect).

### Additional Product information



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Ascophyllum nodosum whole plant Powder	150 mg
Fucus vesiculosus whole plant Extract dry concentrate	120 mg
Equivalent: Fucus vesiculosus (Dry)	600 mg
Other Ingredients (Excipients)	
hypromellose	
magnesium stearate	
microcrystalline cellulose	
silicon dioxide	

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