



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

## Public Summary

<b>Summary for ARTG Entry:</b>	340514	BLACKMORES LUTEIN-VISION ADVANCED
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Blackmores Ltd	
<b>Postal Address</b>	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
<b>ARTG Start Date</b>	30/07/2020	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . BLACKMORES LUTEIN-VISION ADVANCED

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	30/07/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support healthy eye function  
Maintain/support eye health  
Helps maintain/support eye macula health  
Helps maintain/support eye retina health  
Maintain/support healthy eyesight/vision

#### Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

#### Additional Product information

#### Pack Size/Poison information

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

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>concentrated fish Omega-3 triglycerides</b>	<b>850 mg</b>
Equivalent: docosahexaenoic acid	176 mg
Equivalent: eicosapentaenoic acid	352 mg
<b>selenomethionine</b>	<b>124.19 microgram</b>
Equivalent: selenium	50 microgram
<b>zeaxanthin</b>	<b>.9996 mg</b>

**Other Ingredients (Excipients)**

ascorbyl palmitate  
colloidal anhydrous silica  
Gelatin  
glycerol  
hydrogenated vegetable oil  
iron oxide black  
iron oxide red  
lecithin  
medium chain triglycerides  
mixed (low-alpha type) tocopherols concentrate  
Olive Oil  
purified water  
Safflower Oil  
Soya Oil  
vanillin  
yellow beeswax

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