



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	8/06/2022 10:56:47 AM
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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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

concentrated fish Omega-3 triglycerides	850 mg
Equivalent: eicosapentaenoic acid	352 mg
Equivalent: docosahexaenoic acid	176 mg
selenomethionine	124.19 microgram
Equivalent: selenium	50 microgram
Tagetes erecta	66.5 mg
Equivalent: Tagetes erecta (Fresh)	5054 mg
Equivalent: Lutein esters calculated as lutein (of Tagetes erecta) ()	9.975 mg
zeaxanthin	.9996 mg

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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