



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	317969	BLACKMORES MACU-VISION PLUS
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	28/05/2019	
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.

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 MACU-VISION PLUS

Product Type	Single Medicine Product	Effective Date	18/11/2021
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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
Maintain/support eye health in aging individuals
Helps maintain/support eye macula health
Helps maintain/support eye retina health
Maintain/support healthy eyesight/vision
Maintain/support general health and wellbeing

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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1



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Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	250 mg
cupric oxide	1.25 mg
Equivalent: copper	1 mg
d-alpha-tocopheryl acid succinate	165.2 mg
Equivalent: d-alpha-tocopheryl acid succinate	200 IU
lutein	5 mg
zeaxanthin	1 mg
zinc oxide	49.6 mg
Equivalent: zinc	40 mg

Other Ingredients (Excipients)

ascorbyl palmitate
Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium
ethylcellulose
hypromellose
iron oxide yellow
macrogol 400
macrogol 8000
magnesium stearate
maize starch
microcrystalline cellulose
purified talc
sodium chloride
sodium starch glycollate
titanium dioxide

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