



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	392695 UC Promega
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102 Australia
ARTG Start Date	25/07/2022
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 . UC Promega

Product Type	Single Medicine Product	Effective Date	25/07/2022
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Permitted Indications

Helps maintain/support eye retina health
Maintain/support healthy eyesight/vision
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Maintain/support cardiovascular system health
Maintain/support heart health

Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to serious cardiovascular conditions.
Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
Contains fish OR Contains fish products.

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 Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

Clupea harengus lipid extract	232.05 mg
Equivalent: docosahexaenoic acid	39.27 mg
Equivalent: eicosapentaenoic acid	14.28 mg
concentrated fish Omega-3 triglycerides	300 mg
Equivalent: eicosapentaenoic acid	30 mg
Equivalent: docosahexaenoic acid	141 mg

Other Ingredients (Excipients)

Gelatin

glycerol

medium chain triglycerides

purified water

vanillin

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