



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	254618	Kyani Sunset
ARTG entry for	Medicine Listed	
Sponsor	Kyani Australia Pty Ltd	
Postal Address	Suite A Level 2 / 5 Belmore Street, BURWOOD, NSW, 2134 Australia	
ARTG Start Date	12/08/2015	
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 . Kyani Sunset

Product Type	Single Medicine Product	Effective Date	18/12/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support healthy eyesight/vision
Maintain/support cardiovascular system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
If product is indicated for supplementation, 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 serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.
The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

colecalfiferol	8.3 microgram
concentrated fish Omega-3 triglycerides	200 mg
Equivalent: eicosapentaenoic acid	106 mg
Equivalent: docosahexaenoic acid	40 mg
d-alpha-tocopherol	3.36 mg
natural fish oil	112.32 mg
Equivalent: docosahexaenoic acid	6.75 mg
Equivalent: eicosapentaenoic acid	6.75 mg
palm tocotrienols complex	88 mg
retinol palmitate	458.15 microgram
Equivalent: vitamin A	249.9 microgram

Other Ingredients (Excipients)

dl-alpha-tocopherol
Gelatin
glycerol
mixed (low-alpha type) tocopherols concentrate
purified water
Soya Oil

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