



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	336051	METAGENICS SLEEPX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	8/05/2020	
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 . METAGENICS SLEEPX

Product Type	Single Medicine Product	Effective Date	2/06/2020
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

- Maintain/support eye health
- Aids/assists eye adaption to variations in light intensity/night vision
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support muscle relaxation
- Maintain/support nervous system function
- Maintain/support healthy sleeping patterns
- Help establish/restore/reset sleep-wake cycle (circadian rhythm)

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 mental illnesses, disorders or 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

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- If you are pregnant, or considering becoming pregnant, do not take without consulting a health professional' (or words to that effect).
- Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

lutein	3.509 mg/g
magnesium amino acid chelate	526.32 mg/g
Equivalent: magnesium	52.63 mg/g
ornithine monohydrochloride	70.18 mg/g
Withania somnifera root Extract dry concentrate	21.93 mg/g
Equivalent: Withania somnifera (Dry)	109.65 mg/g
Withania somnifera leaf Extract dry concentrate	21.93 mg/g
Equivalent: Withania somnifera (Dry)	109.65 mg/g
zeaxanthin	.702 mg/g

Other Ingredients (Excipients)

citric acid

dl-alpha-tocopherol

Flavour

liquid glucose

maize starch

malic acid

mixed (high-alpha type) tocopherols concentrate

potable water

silicon dioxide

sodium ascorbate

starch sodium octenyl succinate

Steviol glycosides

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary