Public Summary

Summary for ARTG Entry:	67507 METAGENICS ENDURA LEMON/LIME FLAVOUR
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	18/01/1999
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 ENDURA LEMON/LIME FLAVOUR

Product Type Single Medicine Product **Effective Date** 21/05/2020

Permitted Indications

Enhance/promote/physical endurance/capacity/stamina
Restore body fluid balance during high intensity exercise
Decrease/reduce/relieve symptoms of dehydration during high intensity exercise
Helps restore body electrolyte balance during high intensity exercise
Decrease/reduce/relieve muscle cramps
Helps reduce occurrence of muscle cramp
Helps decrease/reduce/relieve mild muscle spasms/twitches
Maintain/support muscle function
Decrease/reduce/relieve muscle pain/ache/soreness
Helps enhance/improve/promote/increase muscle performance/endurance/stamina
Maintain/support muscle performance/endurance/stamina during high intensity exercise
Helps enhance/improve/promote/increase physical/exercise performance

Indication Requirements

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to mild fluid retention.
Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
If symptoms persist consult your healthcare practitioner (or words to that effect).
The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).

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

calcium amino acid chelate	**8.4 mg/g**
Equivalent: calcium	1.7 mg/g
magnesium amino acid chelate	**65 mg/g**
Equivalent: magnesium	6.5 mg/g
monobasic potassium phosphate	**16.75 mg/g**
Equivalent: potassium	4.8 mg/g
sodium chloride	**6.33 mg/g**
Equivalent: sodium	2.5 mg/g

Other Ingredients (Excipients)

Flavour
fructose
malic acid
maltodextrin