



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	409774	Electrolytes
ARTG entry for	Medicine Listed	
Sponsor	MTHFR Support Australia Pty Ltd	
Postal Address	PO Box 1265, Neutral Bay Junction, NSW, 2089 Australia	
ARTG Start Date	30/05/2023	
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 . Electrolytes

Product Type	Single Medicine Product	Effective Date	30/05/2023
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Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Maintain/support body electrolyte balance
Helps maintain/support healthy acid/alkali balance in the body
Maintain/support general health and wellbeing
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support healthy immune system function
Maintain/support healthy muscle contraction function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral) within normal range
Maintain/support nerve conduction
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support kidney function

Indication Requirements

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased



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physical activity.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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 chronic fatigue syndrome.

Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(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].

The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).

Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder
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Route of Administration	Oral
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Visual Identification

Active Ingredients

creatine monohydrate	27.78 mg/g
glucose	141.11 mg/g
inositol	22.22 mg/g
magnesium citrate	111.11 mg/g
Equivalent: magnesium	16.67 mg/g
potassium chloride	108.98 mg/g
Equivalent: chloride	52.2 mg/g
Equivalent: potassium	56.78 mg/g
ribose	222.22 mg/g
sodium chloride	65.36 mg/g
Equivalent: sodium	25.56 mg/g
Equivalent: chloride	39.8 mg/g
taurine	39.61 mg/g

Other Ingredients (Excipients)

Flavour

malic acid

potassium bicarbonate

thaumatin

Public Summary

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