



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	352656	Para Tone
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	7/01/2021	
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 . Para Tone

Product Type	Single Medicine Product	Effective Date	11/01/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support healthy blood circulation
- Maintain/support heart health
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve excess intestinal gas
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Maintain/support mental concentration/focus/clarity
- Maintain/support cognitive function/mental function
- Maintain/support nerve conduction

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Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system health
 Maintain/support nervous system function

Indication Requirements

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

Product presentation must not imply or refer to any thyroid related diseases.

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to chronic fatigue syndrome.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious immunological diseases.

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

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

acetyl levocarnitine hydrochloride	148.67 mg
ascorbic acid	60 mg
Biotin	80 microgram
Brassica oleracea var. italica herb Extract dry concentrate	37.5 mg
Equivalent: Brassica oleracea var. italica (Dry)	750 mg
calcium pantothenate	9.83 mg
Equivalent: pantothenic acid	9 mg
Capsicum annuum fruit Extract dry concentrate	8.33 mg
Equivalent: Capsicum annuum (Dry)	50 mg
d-alpha-tocopheryl acetate	7.35 mg
Equivalent: d-alpha-tocopherol	6.71 mg
Eleutherococcus senticosus root Extract dry concentrate	50 mg
Equivalent: Eleutherococcus senticosus (Dry)	750 mg
inositol	50 mg
levomefolate glucosamine	90 microgram
Equivalent: levomefolic acid	50 microgram
lysine hydrochloride	12.5 mg



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Equivalent: lysine	10 mg
manganese (II) glycinate	3.695 mg
Equivalent: manganese	1 mg
nicotinamide	20 mg
Piper nigrum fruit Extract dry concentrate	16 microgram
Equivalent: Piper nigrum (Dry)	400 microgram
potassium iodide	91.8 microgram
Equivalent: iodine	70.18 microgram
potassium sulfate	78 mg
Equivalent: potassium	35 mg
pyridoxal 5-phosphate monohydrate	3.14 mg
Equivalent: pyridoxine	2 mg
quercetin	50 mg
selenomethionine	50 microgram
Equivalent: selenium	20.13 microgram
serine	5 mg
thiamine hydrochloride	2.24 mg
Equivalent: thiamine	2 mg
tyrosine	10 mg
Withania somnifera root Extract dry concentrate	25 mg
Equivalent: Withania somnifera (Dry)	250 mg
zinc glycinate monohydrate	10.64 mg
Equivalent: zinc	3 mg
Zingiber officinale rhizome Extract dry concentrate	10 mg
Equivalent: Zingiber officinale (Dry)	250 mg

Other Ingredients (Excipients)

Arthrospira platensis
calcium carbonate
calcium hydrogen phosphate
calcium sulfate
Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium
hypromellose
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water
riboflavin
rice starch
silicified microcrystalline cellulose
silicon dioxide
stearic acid
Sunflower Oil

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