



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	358733	ThyroSense
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	1/04/2021	
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 . ThyroSense

Product Type	Single Medicine Product	Effective Date	1/04/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
Traditionally used in Ayurvedic medicine to maintain/support energy levels
Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Enhance/promote body adaptation to stress
Traditionally used in Ayurvedic medicine to enhance/promote body adaptation to stress
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Support healthy stress response in the body
Decrease/reduce/relieve symptoms of stress
Traditionally used in Ayurvedic medicine to maintain/support mental concentration/focus/clarity
Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
Maintain/support cognitive function/mental function
Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to chronic fatigue syndrome.



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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).

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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.

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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bacopa monnieri leaf Extract dry concentrate	25 mg
Equivalent: Bacopa monnieri (Dry)	4.75 g
calcium pantothenate	54.348 mg
Equivalent: pantothenic acid	50 mg
copper gluconate	1.786 mg
Equivalent: copper	250 microgram
manganese sulfate monohydrate	.769 mg
Equivalent: manganese	250 microgram
potassium iodide	98.168 microgram
Equivalent: iodine	75 microgram
selenomethionine	62.09 microgram
Equivalent: selenium	25 microgram
tyrosine	250 mg
Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.5 g
zinc sulfate monohydrate	13.736 mg
Equivalent: zinc	5 mg
Zingiber officinale root Extract dry concentrate	20 mg
Equivalent: Zingiber officinale (Dry)	500 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- calcium hydrogen phosphate
- colloidal anhydrous silica
- croscarmellose sodium
- hypromellose
- magnesium stearate
- microcrystalline cellulose

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Oryza sativa

stearic acid

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