



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	317517	Selenium Forte 150 mcg
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Ltd	
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia	
ARTG Start Date	13/05/2019	
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 . Selenium Forte 150 mcg

Product Type	Single Medicine Product	Effective Date	5/02/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support healthy thyroid hormones
Maintain/support immune system health
Enhance/improve/promote immune defence/immunity
Helps enhance/improve/promote immune system function
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Helps stimulate a healthy immune system response
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Help maintain/support emotional wellbeing
Decrease/reduce/relieve symptoms of mild anxiety
Helps reduce occurrence of symptoms of mild anxiety
Support healthy emotional/mood balance
Maintain/support female reproductive system health
Maintain/support reproductive system health in adults
Helps enhance/promote prostate health
Maintain/support semen health
Maintain/support sperm motility
Maintain/support sperm production

Indication Requirements

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



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

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.

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

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

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

Product presentation must only refer to mild anxiety.

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

selenomethionine	375 microgram
Equivalent: selenium	150 microgram

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

hypromellose

magnesium stearate

maltodextrin

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