



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	150619	Selenium 150 MAX
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	11/03/2008	
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 150 MAX

Product Type	Single Medicine Product	Effective Date	7/07/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support general health and wellbeing
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support reproductive system health in males
Helps maintain/support testosterone formation/synthesis
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support sperm production

Indication Requirements

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

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 any thyroid related diseases.

Product presentation must not imply or refer to infertility.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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.
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	372.2 microgram
Equivalent: selenium	150 microgram

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

carrageenan

hypromellose

magnesium stearate

microcrystalline cellulose

potassium acetate

purified water

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