



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	377812	E Asta Sel
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	12/11/2021	
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 . E Asta Sel

Product Type	Single Medicine Product	Effective Date	17/12/2021
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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
- Aid/assist thyroid hormone production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support preconception health in healthy males
- Maintain/support reproductive system health in males
- Maintain/support sperm health in healthy males
- Maintain/support sperm motility in healthy males
- Maintain/support sperm production in healthy males
- Maintain/support wound healing

Indication Requirements

- Product presentation must not imply or refer to infertility.
- Product presentation must not imply or refer to serious immunological diseases.
- 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.
- If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications



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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, soft

Route of Administration Oral

Visual Identification

Active Ingredients

astaxanthin esters extracted from Haematococcus pluvialis	20 mg
Equivalent: Astaxanthin (of Haematococcus pluvialis)	2 mg
Bixa orellana seed Distillate concentrate	32.5 mg
Equivalent: Bixa orellana (Dry)	10.8225 g
mixed (high-alpha type) tocopherols concentrate	37.802 mg
Equivalent: d-alpha-tocopherol	36.24 mg
mixed (low-alpha type) tocopherols concentrate	82.666 mg
Equivalent: d-alpha-tocopherol	30.71 mg
palm tocotrienols complex	19.935 mg
selenomethionine	123.4 microgram
Equivalent: selenium	49.675 microgram

Other Ingredients (Excipients)

calcium hydrogen phosphate
Carnauba Wax
glycerol
medium chain triglycerides
modified food starch
Palm Fruit Oil
PEG-35 castor oil
purified water
sorbitol
Sunflower Oil
vanillin

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