



**Australian Government**  
**Department of Health**  
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 any thyroid related diseases.

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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 infertility.

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

### 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

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

Public Summary

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