



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	358732	MyO-Sense
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	1/04/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . MyO-Sense

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	11/05/2021
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support cardiovascular system health
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps decrease/reduce homocysteine levels
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
- Maintain/support female reproductive system health
- Maintain/support/regulate healthy menstrual cycle
- Maintain/support preconception health in healthy females
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones
- Maintain/support testosterone level

#### Indication Requirements

- Product presentation must not imply or refer to infertility.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- Product presentation must not imply or refer to hormone imbalances.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications



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No Specific Indications included on Record

**Warnings**

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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** Powder  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>chromic chloride hexahydrate</b>	<b>128.107 microgram/g</b>
Equivalent: chromium	25 microgram/g
<b>chromium picolinate</b>	<b>67.015 microgram/g</b>
Equivalent: chromium	8.33 microgram/g
<b>colecalfiferol</b>	<b>.0041 mg/g</b>
<b>inositol</b>	<b>666.67 mg/g</b>
<b>levomefolate calcium</b>	<b>72.18 microgram/g</b>
Equivalent: levomefolic acid	66.67 microgram/g
<b>mecobalamin (co-methylcobalamin)</b>	<b>.5 microgram/g</b>
<b>quercetin dihydrate</b>	<b>83.3211 mg/g</b>
<b>selenomethionine</b>	<b>62.09 microgram/g</b>
Equivalent: selenium	25 microgram/g
<b>zinc citrate dihydrate</b>	<b>5.227 mg/g</b>
Equivalent: zinc	1.67 mg/g

**Other Ingredients (Excipients)**

- calcium carbonate
- calcium hydrogen phosphate
- colloidal anhydrous silica
- dl-alpha-tocopherol
- dl-alpha-tocopheryl acetate
- ethoxylated hydrogenated castor oil
- fractionated coconut oil
- lecithin
- maltodextrin
- medium chain triglycerides
- mono- and di- glycerides
- Oryza sativa
- purified water
- silicon dioxide
- sodium ascorbate
- starch sodium octenyl succinate
- sucrose

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