



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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 hormone imbalances.
- 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 infertility.
- 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 serious cardiovascular conditions.
- If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

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