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

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 serious cardiovascular conditions.

Product presentation must not imply or refer to infertility.

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

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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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
colecalciferol	**.0041 mg/g**
inositol	**666.67 mg/g**
levomefolate calcium	**72.18 microgram/g**
Equivalent: levomefolic acid	66.67 microgram/g
mecobalamin (co-methylcobalamin)	**.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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