



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371983	HM-Clear
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	2/08/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . HM-Clear

Product Type	Single Medicine Product	Effective Date	10/09/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support natural body cleansing/detoxification processes
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to decrease/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to decrease/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to antispasmodic/spasmodic
- Helps decrease/reduce homocysteine levels
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support cognitive function/mental function
- Maintain/support nervous system function
- Traditionally used in Western herbal medicine to decrease/relieve mild upper respiratory tract congestion
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Product presentation must not imply or refer to disease in any body organ.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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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 drugs/alcohol.

Respiratory tract infections must be qualified by 'mild'.

Product presentation must only refer to detoxification in relation to natural body processes.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

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 and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Not recommended for use by pregnant and lactating women (or words to that effect).

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

Allium sativum bulb Powder	114.29 mg/g
Equivalent: Allium sativum (Fresh)	1.1429 g/g
alpha lipoic acid	114.29 mg/g
ascorbic acid	285.71 mg/g
glutathione	71.43 mg/g
high selenium yeast	33.33 mg/g
Equivalent: selenium	40 microgram/g
levomefolate glucosamine	203.399 microgram/g
Equivalent: levomefolic acid	114.29 microgram/g
manganese sulfate monohydrate	703.076 microgram/g
Equivalent: manganese	228.57 microgram/g
zinc citrate dihydrate	17.886 mg/g
Equivalent: zinc	5.71 mg/g

Other Ingredients (Excipients)

Flavour

maltodextrin

Oryza sativa

Steviol glycosides

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