

Australian Government

### **Department of Health**

## Therapeutic Goods Administration

### Public Summarv

Summary for ARTG Entry:	374479	DetoxClear
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 So Australia	buth Street, Rydalmere, NSW, 2116
ARTG Start Date	10/09/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicine	s
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. DetoxClear Product Type Effective Date 10/09/2021 Single Medicine Product **Permitted Indications** Antioxidant/Reduce free radicals formed in the body Helps reduce/decrease free radical damage to body cells Aids/assists natural body cleansing/detoxification processes Maintain/support natural body cleansing/detoxification processes Maintain/support natural liver cleansing/detoxification processes Maintain/support body mucous membrane health Maintain/support body tissue repair/regeneration Maintain/support healthy mucous linings of the digestive system Maintain/support digestive system health after exercise Maintain/support gastrointestinal system health after exercise Maintain/support gastrointestinal mucosal membrane health Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow Traditionally used in Western herbal medicine to helps enhance/promote healthy liver function Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver Traditionally used in Western herbal medicine to maintain/support healthy liver function Maintain/support healthy liver function Maintain/support immune system health Maintain/support immune system health Maintain/support immune system health after exercise Maintain/support healthy immune system function Indication Requirements Product presentation must not imply or refer to serious immunological diseases. Product presentation must not imply or refer to drugs/alcohol. 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 gastro oesophageal reflux disease. Produced at 17.03.2022 at 04:07:19 AEDT Page 1 of 3 This is not an ARTG Certificate document.



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Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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

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

### **Standard Indications** No Standard Indications included on Record **Specific Indications** No Specific Indications included on Record Warnings Adults only. **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 222.22 mg/g Arthrospira platensis Brassica oleracea var. italica seed Extract dry concentrate 5.5575 mg/g Equivalent: Brassica oleracea var. italica (Dry) 85.5 mg/g Camellia sinensis leaf Extract dry concentrate 22.22 mg/g Equivalent: Camellia sinensis (Dry) 666.66 mg/g Chlorella vulgaris whole plant Powder 222.22 mg/g glutamine 185.19 mg/g glycine 37.04 mg/g levomefolate glucosamine 32.957 microgram/g Equivalent: levomefolic acid 18.5185 microgram/g mecobalamin (co-methylcobalamin) 37.04 microgram/g Punica granatum fruit hull Extract dry concentrate 1.85 mg/g Equivalent: Punica granatum (Dry) 37 mg/g pyridoxal 5-phosphate monohydrate 1.3587 mg/g Equivalent: pyridoxine 930 microgram/g quercetin dihydrate 11.1411 mg/g retinol palmitate 30.525 microgram/g Equivalent: vitamin A 16.65 microgram/g Silybum marianum seed Extract dry concentrate standardised 18.52 mg/g Equivalent: Silybum marianum (Dry) 555.6 mg/g

### Other Ingredients (Excipients)

aluminium sodium silicate aluminium starch octenylsuccinate butylated hydroxytoluene citric acid colloidal anhydrous silica dl-alpha-tocopheryl acetate ethoxylated hydrogenated castor oil Flavour

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fractionated coconut oil Gelatin Guar Gum lecithin maltodextrin mono- and di- glycerides Oryza sativa potable water silicon dioxide Siraitia grosvenorii Steviol glycosides sucrose

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