



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	371416	DioxiClear
<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>	21/07/2021	
<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 . DioxiClear

Product Type	Single Medicine Product	Effective Date	24/11/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes  
Helps maintain/support healthy cholesterol  
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 immune system health  
Maintain/support healthy immune system function  
Maintain/support (state vitamin/mineral/nutrient) levels in the body

### Indication Requirements

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range  
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.  
Label statement: If symptoms persist, talk to your health professional.

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 encourage excessive or harmful consumption of alcohol or other toxic substances.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to drugs/alcohol.

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

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.

### Standard Indications

No Standard Indications included on Record



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**Specific Indications**

No Specific Indications included on Record

**Warnings**

Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication.  
Do not take powder alone. Mix with food or fluid.  
Contains crustacea OR Contains crustacean products.

**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**

ascorbic acid	60.61 mg/g
Guar Gum	545.45 mg/g
mixed (low-alpha type) tocopherols concentrate	16.24 mg/g
poliglusam	105.45 mg/g
quercetin dihydrate	36.36 mg/g
<b>Silybum marianum seed Extract dry concentrate standardised</b>	<b>31.82 mg/g</b>
Equivalent: Silybum marianum (Dry)	954.6 mg/g

**Other Ingredients (Excipients)**

Acacia  
chlorophyllin-copper complex  
citric acid  
colloidal anhydrous silica  
dl-alpha-tocopheryl acetate  
ethoxylated hydrogenated castor oil  
Flavour  
fractionated coconut oil  
lecithin  
mono- and di- glycerides  
Oryza sativa  
potable water  
Soya Oil  
Steviol glycosides

Public Summary

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