



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371416	DioxiClear
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	21/07/2021	
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 . 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 liver disease, such as cirrhosis, hepatitis.
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.
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).
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

Do not take powder alone. Mix with food or fluid.

Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication.

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
Silybum marianum seed Extract dry concentrate standardised	31.82 mg/g
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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