



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	411129	Fucoimmune
ARTG entry for	Medicine Listed	
Sponsor	Marine Nature Pharmaceuticals Australia Pty Ltd	
Postal Address	29/14 Narrabang Way, Belrose, NSW, 2085 Australia	
ARTG Start Date	23/06/2023	
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 . Fucoimmune

Product Type	Single Medicine Product	Effective Date	30/11/2023
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Aid/assist healthy red blood cell production
- Maintain/support blood capillary health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support skin health
- Maintain/support wound healing

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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
magnesium citrate	154.33 mg
Equivalent: magnesium	25 mg
pyridoxine hydrochloride	25 mg
Equivalent: pyridoxine	20.5 mg
Undaria pinnatifida spore Extract dry concentrate	117.65 mg
Equivalent: Undaria pinnatifida (Dry)	1.412 g
zinc gluconate	55.75 mg
Equivalent: zinc	8 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose

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