

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	405873	Vital Vegan Omega-3
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasan	nce Pty Ltd
Postal Address	PO Box 2007, SO Australia	OUTH MELBOURNE, VIC, 3205
ARTG Start Date	7/03/2023	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	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

Product Type	Single Medicine Product	Effective Date	10/03/2023	
Permitted Indication	ons			
Maintain/support he	ealthy eye function			
Maintain/support ey	ve health			
Maintain/support ge	eneral health and wellbeing			
Helps in the mainte	nance of healthy blood lipids/blood fats			
Maintain/support ca	rdiovascular system health			
Helps maintain/sup	port healthy heart function			
Maintain/support he	ealthy cardiovascular system function			
Maintain/support co	gnitive function/mental function			
Maintain/support ge	eneral mental wellbeing			
Maintain/support br	ain function			
Maintain/support he	ealthy pregnancy			
Indication Require	ements			
Product presentation	on must not imply or refer to vision correction,	faults or serious eye disease e.g.	macular degeneration.	
Product presentation	on must not imply or refer to serious cardiovas	cular conditions.		
Label statement: A	dvise your doctor of any medicine you take du	rring pregnancy, particularly in you	ur first trimester.	
Product presentation	on must not imply or refer to mental illnesses,	disorders or conditions.		
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.				
Standard Indicatio	ns			
No Standard Indica	tions included on Record			
Specific Indication	IS			
No Specific Indicati	ons included on Record			
Warnings				
No Warnings includ	led on Record			
Additional Produc	t information			
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Therapeutic Goods Administration

Pack Size Poison Schedule Components 1. Formulation 1 Dosage Form Capsule, soft Route of Administration Oral Visual Identification Oral DHA/EPA rich Schizochytrum atgal oil Guivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp. 265 mg Equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp. 255 mg equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp. 265 mg equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp. 255 mg equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp. 255 mg inited (low-alpha type)-to-to-to-to-to-to-to-to-to-to-to-to-to-	Pack Size/Poison informatio	n	
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