



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370695	Opti EPA/DHA Plus SPM
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	7/07/2021	
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 . Opti EPA/DHA Plus SPM

Product Type	Single Medicine Product	Effective Date	23/07/2021
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Permitted Indications

Maintain/support eye health
Anti-inflammatory/relieve inflammation
Helps in the maintenance of healthy blood lipids/blood fats
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support cognitive function/mental function
Maintain/support brain health
Helps maintains/support healthy foetal CNS/brain development

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to serious cardiovascular conditions.
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 imply or refer to lowering blood lipids, blood fats and triglycerides.
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule soft enteric

Route of Administration Oral

Visual Identification

Active Ingredients

concentrated fish Omega-3 triglycerides	650 mg
Equivalent: eicosapentaenoic acid	312 mg
Equivalent: docosahexaenoic acid	208 mg
Equivalent: docosapentaenoic acid	9.75 mg

Other Ingredients (Excipients)

Gelatin

glycerol

pectin

purified water

sorbitol

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