

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	412755 P	PhytoLove Ahiflower Oil	
ARTG entry for	Medicine Listed		
Sponsor	Phytolove Pty Ltd		
Postal Address	701 Left Bank Road, Mullumbimby Creek, NSW, 2482 Australia		
ARTG Start Date	6/07/2023		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines		
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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. PhytoLove Ahiflower Oil

Product Type Single Medicine Product

Permitted Indications

Effective Date

26/03/2025

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Maintain/support general health and wellbeing

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Aid/assist/helps synthesis of (insert vitamin) in the body

Indication Requirements

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)

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: Vitamins can only be of assistance if the dietary vitamin intake is inadequate OR Vitamin supplements should not replace a balanced diet.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken by children under 3 years old (or words to that effect).

Additional Product information

Pack Size/Poison information	1	
Pack Size		Poison Schedule
Components		
1. Formulation 1		
Dosage Form Route of Administration	Capsule, soft	

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Department of Health and Aged Care Therapeutic Goods Administration

Oral

Visual Identification

Active Ingredients

refined Buglossoides arvensis seed oil

Other Ingredients (Excipients)

glycerol modified food starch purified water sorbitol vanillin 772 mg

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