Public Summary

Summary for ARTG Entry:	119911 Algotene
ARTG entry for	Medicine Listed
Sponsor	Interclinical Laboratories Pty Ltd
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	15/06/2005
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 . Algotene

Product Type Single Medicine Product **Effective Date** 21/06/2021

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support eye health
Maintain/support healthy eyesight/vision
Maintain/support general health and wellbeing
Maintain/support immune system health
Maintain/support healthy immune system function

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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	
Dunaliella salina whole plant Dry	**500 mg**

Other Ingredients (Excipients)
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate