



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	332688	Iodine Drops
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	27/03/2020	
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 . Iodine Drops

Product Type	Single Medicine Product	Effective Date	18/01/2023
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid gland function in children
Maintain/support healthy thyroid hormones in children
Maintain/support healthy thyroid hormones
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Aid/assist thyroid hormone production in children
Aid/assist thyroid hormone production

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.
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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.
Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Additional Product information

Pack Size/Poison information



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

potassium iodide	3.334 mg/mL
Equivalent: potassium	784 microgram/mL
Equivalent: iodine	2.55 mg/mL

Other Ingredients (Excipients)

carmellose sodium

ethanol

Flavour

glycerol

potassium sorbate

purified water

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary