

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 310363 METAGENICS LIQUID IODINE

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 15/10/2018

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. METAGENICS LIQUID IODINE

Product Type Single Medicine Product Effective Date 10/07/2023

Permitted Indications

Maintain/support healthy thyroid gland function

Maintain/support healthy thyroid hormones

Maintain/support thyroid gland health

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breastfeeding women

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy adults

Maintain/support brain/central nervous system development in breastfeeding women

Maintain/support brain/central nervous system development in breast fed healthy infants

Maintain/support healthy pregnancy

Indication Requirements

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

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 directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to neurological conditions or developmental delays.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

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Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormOral LiquidRoute of AdministrationOral

Visual Identification

Active Ingredients

 potassium iodide
 3.499 mg/mL

 Equivalent: iodine
 2.67 mg/mL

 Equivalent: potassium
 .824 mg/mL

Other Ingredients (Excipients)

ethanol absolute

Flavour

glycerol

purified water

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