



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	314850	Orthoplex Iodine
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	27/02/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Orthoplex Iodine

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/02/2021
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### Permitted Indications

Maintain/support body metabolism/metabolic rate  
Maintain/support healthy growth and development  
Maintain/support general health and wellbeing  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Maintain/support thyroid gland health  
Aid/assist thyroid hormone production  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support cognitive development  
Maintain/support brain/central nervous system development  
Helps maintains/support healthy foetal CNS/brain development  
Maintains/support healthy foetal development  
Maintain/support healthy pregnancy  
Maintain/support maternal health  
Aid/assist healthy thyroid hormone production for pregnancy  
Maintain/support healthy thyroid gland function for pregnancy

### Indication Requirements

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

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

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

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

Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.

Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased



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physical activity.

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 neurological conditions or developmental delays.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

**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**

<b>potassium iodide</b>	<b>294 microgram</b>
Equivalent: iodine	225 microgram

**Other Ingredients (Excipients)**

colloidal anhydrous silica

disodium edetate

gellan gum

glycine

hypromellose

leucine

potable water

potassium acetate

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